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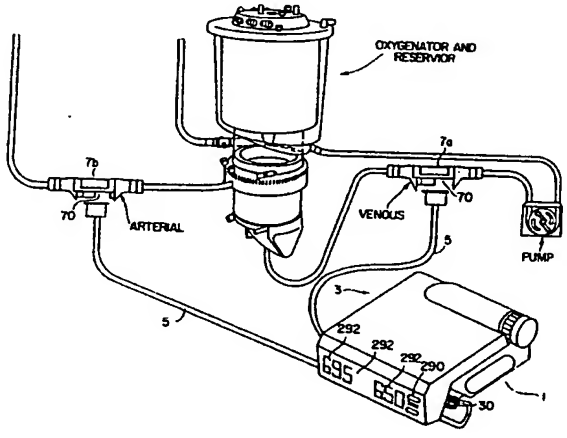
(57) Abstract

Blood is passing through a blood circuit where it is exposed to light at red and infrared wavelength. The amount of light reflected is measured at a single distance from the provided infrared light and is used to calculate the hematocrit level. Oxygen saturation is then calculated. In another method, different formulas are used, selected according to the oxygen saturation and/or the hematocrit level. In one embodiment, hematocrit level is determined using measurement of reflected infrared light at the isobestic wavelength of oxy- and deoxyhemoglobin. In another, hematocrit level is determined using measurements of reflected infrared light at two wavelenghts symmetrically disposed about the isobestic wavelength in order to approximate the measurement at this point. The oxygen saturation calculation is based in part on the ratio of the measurement at an infrared wavelength to a separate one measured at a red wavelength. Particular apparatus including LEDs (20, 22, 24), fiber-optic cables (5) is also disclosed, together with instrumentation (3) for operating the device and effecting the determinations.



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METHOD AND APPARATUS FOR DETERMINING OXYGEN SATURATION

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to fiber-optic sensors for determining oxygen saturation and hematocrit of the blood as it flows through an extracorporeal blood circuit in which it is oxygenated during bypass surgery and the like.

Description of the Prior Art

Fiber-optic sensors for the determination of oxygen saturation (amount of oxygenated hemoglobin), and/or the determination of hematocrit (amount of red blood cells), in the blood in an extracorporeal circuit or otherwise are disclosed in U.S. Patents 4,444,498, 4,447,150, 4,651,741, 4,745,279, 4,776,340 and others. Many such sensors function by providing light to the blood sample via a fiber-optic cable, and measuring the amount of reflected or transmitted light. Light-emitting diodes (LEDs) have been used in these devices to provide radiation at given wavelengths to the sample via the fiber-optic input cables; other fiber-optic cables have transmitted the light reflected by or transmitted through the sample at those wavelengths to photodiodes to produce a current proportionate to the reflected or transmitted light. In general, the LEDs alternately, or in series, emit light of one wavelength and then another. See Heinemann, U.S. Patent 4,444,498, Lavallee, U.S. Patent 3,647,299, Goldring, U.S. Patent 4,684,245. The calculation of both hematocrit and oxygen saturation allow calculation of approximately the total oxygen content of the blood.

Hematocrit has been calculated in such devices from a ratio of the amount of light reflected from the blood at two different

distances from the light source; the isobestic point on the oxy and deoxyhemoglobin reflection curves (about 820 nm) is the wavelength suggested because it is not influenced by the oxygen saturation level. Two detectors are used to receive the reflected light at two different distances from the source, all as disclosed in Moran, U.S. Patent 4,776,340, and Schmitt, et al, *An Integrated Circuit-Based Optical Sensor for In Vivo Measurement of Blood Oxygenation, Vol. BME-33, No. 2 IEEE:* Transactions on Biomedical Engineering, February 1986.

In Steinke, et al., *Reflectance Measurements of Hematocrit and Oxyhemoglobin Saturation*, American Journal Physiology 1987, pp H147 to H153 and Schmitt, et al., *New Methods for Whole Blood Oximetry* 1986, Pergamom Press Ltd., hematocrit is similarly determined, but with two sources at different distances from a single detector. These systems always, however, require three channels to calculate hematocrit, either two source channels and one detector or vice versa. In the Schmitt article, it is further required that the "near" measurement be taken at a higher wavelength than the "far" one.

In Karkar, U.S. Patent 4,745,279, hematocrit in a blood circuit is determined by measuring light diffused by the blood, the light being provided by an LED source adjacent the blood at the isobestic wavelength. A correction is then made for oxygen saturation, and a look-up table used to determine true hematocrit.

In sensors for oxygen saturation, often called oximeters, oxygen saturation has been determined using a number of different equations based on input of light at about 665 nm and about 820 nm, such as:

$sO_2 = A+B(Ratio_0)$ and $sO_2 = A-B\ (Ratio_0)$ where

$$Ratio_0 = \frac{R_{820}}{R_{665}}$$ and A and B are constants,

These equations may depend on the configuration of the particular device. 665 nm is a point of large difference between absorption of deoxyhemoglobin and oxyhemoglobin on the reflection curves; 820 nm or thereabouts is an isobestic point at which the absorption is identical for both compounds.

It was originally thought that the reading at the 820 nm isobestic point in the oxygen saturation calculation would compensate for varying optical density. It was also thought to compensate for varying hematocrit levels because saturation of hemoglobin with oxygen does not influence the amount of reflected light at that point; see Heinemann, U.S. Patent 4,447,150.

However, it has been determined that oxygen saturation results may be inaccurate in certain ranges unless further compensation is made for blood variation. In Shaw, U.S. Patent 4,114,604 and Lubbers, et al., U.S. Patent 3,825,342, a third wavelength is used as well in the measurement of oxyhemoglobin to correct for variability in the blood. In Takatani, et al., *A Miniature Hybrid Reflection Type Optical Sensor for Measurement of Hemoglobin Content and Oxygen Saturation of Whole Blood*, 35 IEEE: Transactions on Biomedical Engineering 3, March 1988, correction for blood variability

was made by adding a constant to the denominator and sometimes also the numerator of $Ratio_0$, the constant being fixed based on blood characteristics and sensor geometry. In Shaw, et al., U.S. Patent 3,847,483, two non-isobestic wavelengths are used for measuring oxygen saturation using a more complex equation, in order to yield a measurement thought to be independent of blood variation.

In Steinke and Shepherd, *Reflectance Measurements of Hematocrit and Oxyhemoglobin Saturation*, American Journal Physiology, 1987, pp H147 to H153, the oxygen saturation figure is corrected for hematocrit by calibrating constants used in the oxygen saturation determination according to the hematocrit level. This approach, however, does not allow correction if hematocrit changes, and thus may introduce error into the system.

The latter of the two Schmitt articles, *New Methods for Whole Blood Oximetry*, 1986, Pergamom Press Ltd. discloses an oxygen saturation measurement made from a device having two identical infrared sources at different distances from the detector, as well as a red light source. Oxygen saturation is measured based on reflected light at these wavelengths using a look-up table which appears to provide an oxygen saturation measurement corrected for variability in hematocrit. However, the Schmitt device requires the separate development and input

of a particular look-up table not only for each instrument, but for each blood-contacting unit used, a lengthy and time-consuming process for any device which is manufactured on other than a custom basis, or which uses disposable blood-contacting units.

Passafaro, U.S. Patent 4,651,741, discloses corrections for hematocrit made using the following equation: $sO_2 = Ak^2I^2 + BkI + C$, where k is a calibration constant and hematocrit is separately measured in the laboratory. In Passafaro, A, B and C are values based on the hematocrit level, contained in a look-up table, and accessed during the calculation. Since laboratory measurements are not instantaneous, the red blood cell level in the blood in the circuit can change radically without a change in the correction factor, resulting in what might be substantial error in the resulting oxygen saturation measurement.

Moran, et al., U.S. Patent 4,776,340 discloses a catheter system in which hematocrit is calculated based on the ratio of reflected infrared light measured at two different distances from the source. No particular wavelength is suggested; instead it is advised not to try to use the isobestic wavelength for the measurements, but to make a correction in the hematocrit calculation instead. An oxygen saturation

calculation includes a compensation for the hematocrit so calculated.

In Shaw, U.S. Patent 4,114,604, two red wavelengths and one infrared are used in the calculation of oxygen saturation in order to minimize its dependence on blood conditions such as hematocrit. The system described includes electronics for calculating oxygen saturation according to two different formulas, depending on the level of oxygen saturation.

Sperinde, et al., U.S. Patent 4,623,248 discloses a fiber-optic catheter oximeter in which the oxygen saturation level of the blood is computed by deriving it with a formula which uses the ratio of one pair of intensity signals when the oxygen saturation level is relatively low and with a formula which uses the ratio of another pair of intensity signals when the oxygen saturation level is high. This, however, while minimizing the effect of hematocrit on the measurement, does not correct for it. Further, it always requires the use of three distinct wavelengths and corresponding LEDs -- two in the red and one in the infrared.

The above description of art is not intended to constitute an admission that any patent, publication or other information referred to is "prior art" or is enabling with respect to this invention, unless specifically designated as such. In addition, this section should not be construed to mean that a

search has been made or that no other pertinent information as defined in 37 C.F.R. § 1.56(a) exists.

Overall, it would be desirable to provide an easily-manufacturable device and a method which provides an oxygen saturation measurement at desired accuracy levels by compensating as necessary for blood variability.

SUMMARY OF THE INVENTION

The present invention is a method and apparatus for determining oxygen saturation in blood passing through a blood circuit which avoids many of the problems associated with prior methods and devices.

In one aspect, the invention is a method of determining oxygen saturation in blood passing through a blood circuit. The method includes the following steps:

providing light to the blood as it passes through the circuit,

receiving light reflected from the blood at a single distance from the provided light,

utilizing the received light to make a representation or approximation of the amount of light reflected from the blood at the isobestic point,

calculating the hematocrit level of the blood passing through the circuit using the representation or approximation made above, and

calculating oxygen saturation in the blood passing through the circuit based on the hematocrit calculation so that the oxygen saturation calculation includes a correction for the hematocrit level calculated as above.

In this aspect, the method of determining oxygen saturation provides an oxygen saturation determination which includes compensation for the hematocrit level of the blood actually concurrently passing through the circuit, without the difficulties of a look-up table or a near/far hematocrit determination.

In this aspect, the light is generally provided at one infrared wavelength and the amount of the infrared light reflected from the blood is measured. Sometimes two infrared wavelengths symmetrically disposed about the isobestic wavelength of oxy- and deoxyhemoglobin are used and the amount of each, reflected from the blood at the same distance from the source, is measured. Generally, red light is also provided to the blood and the amount reflected is measured, so that the oxygen saturation calculation can also be based on the ratio of the amount of infrared-to-red reflected light.

In another aspect, the invention is a method of determining oxygen saturation of the blood which includes the following steps:

providing infrared light to the blood,

providing red light to the blood,

measuring the amount of infrared light returned from the blood,

measuring the amount of red light returned from the blood,

utilizing the measurement of infrared light to calculate hematocrit level, and

calculating oxygen saturation using the following formula:

$$sO_2 = E \cdot Ratio + \frac{F}{Ratio} + \frac{G}{Ratio^2} + H \cdot \frac{Ratio}{Hct} + I \cdot Hct + \frac{J}{Hct} + \frac{K}{Hct^2}$$

E, F, G, H, I, J, K are constants, Hct is the percent hematocrit, and Ratio is the ratio of the measurement of infrared-to-red light returned. This approach has been found to provide a particularly accurate oxygen saturation determination.

In another aspect, though, a different formula is used in the invention, as follows:

$$sO_2 = N \cdot Ratio + \frac{O}{Ratio} + \frac{P}{Ratio^2} +$$

$$Q \cdot \frac{Ratio}{Hct} + S \cdot Hct + T \cdot Ln(Hct)$$

N, O, P, Q, S, and T are constants.

In another aspect, the invention is a method of determining oxygen saturation by using different formulas for the oxygen saturation calculation according to the level of oxygen saturation and/or the level of hematocrit. In one version of this aspect of the invention, the invention includes the following steps:

repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit,

repeatedly measuring light at a wavelength in the infrared reflected from the blood as it passes through the blood circuit,

repeatedly calculating hematocrit level in the blood as it passes through the blood circuit based on the measurements of infrared light, and

repeatedly determining oxygen saturation in the blood based on the hematocrit level, using more than one formula for the determination according to the level of oxygen saturation. This method of determining oxygen saturation is believed to minimize inaccuracies in the result.

In another version of this aspect of the invention, the invention includes the following steps:

repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit,

repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit,

repeatedly calculating oxygen saturation in the blood based on the measurements above, using a different formula for the determination of oxygen saturation depending on the level of hematocrit in the blood. The oxygen saturation calculation also includes a correction for the hematocrit level of the blood. This approach is believed to minimize inaccuracies in the determination of oxygen saturation.

Specific formulas are provided for the calculations of oxygen saturation and hematocrit in the preferred embodiment of these aspects of the invention. Two preferred formulas for the calculation of hematocrit follow.

$$Hct = A \cdot R_{ISOBESTIC} + B \cdot R_{ISOBESTIC}^2 + \frac{C}{R_{ISOBESTIC}} + \frac{D}{R_{ISOBESTIC}^2}$$

$$Hct = Exp\ (L \cdot R_{ISOBESTIC} + M/Ln(R_{ISOBESTIC}^2))$$

Also, it should be noted that in one preferred approach, hematocrit is calculated based on a single measurement of

reflected light at about the isobestic wavelength. In another preferred approach, it is calculated using measurements of reflected light at wavelengths symmetrically disposed about the isobestic point. In the latter case, the amount of light reflected at the isobestic point is approximated by measuring the amount reflected at the different infrared wavelengths and approximating or making a representation of the amount reflected at the isobestic point. The following formulas are preferred for making this approximation and are preferably used when light is provided and measured at two infrared wavelengths:

$$R_{ISOBESTIC} = \frac{R_{FIRST\ INFRARED} + R_{SECOND\ INFRARED}}{2}$$

or

$$R_{ISOBESTIC} = R_{FIRST\ INFRARED} \times R_{SECOND\ INFRARED}$$

In yet another aspect, the invention includes an apparatus for determining oxygen saturation in blood passing through a blood circuit. The apparatus includes:

means for repeatedly providing light to the blood as it passes through the blood circuit,

means for repeatedly receiving light reflected from the blood at a single distance from the provided light,

means for repeatedly utilizing the received light to approximate the amount of light reflected from the blood at the isobestic wavelength of oxy- and deoxyhemoglobin,

means for repeatedly calculating hematocrit level of the blood passing through the blood circuit based on the amount of light reflected from the blood at the isobestic wavelength, and

means for repeatedly calculating oxygen saturation in the blood passing through the blood circuit based on the amount of light reflected from the blood and the calculation of hematocrit so that the oxygen saturation determination includes compensation for the hematocrit level of the blood passing through the circuit, calculated as indicated. Preferably the light is at an infrared wavelength, most preferably at or near the isobestic point.

In this aspect, the apparatus preferably also includes:

means for repeatedly providing light at a red wavelength to the blood,

means for repeatedly measuring the amount of red light reflected from the blood as the blood passes through the blood circuit, and

means for repeatedly measuring the amount of infrared light reflected from the blood as it passes through the blood circuit, where the means for calculating oxygen saturation utilizes the measurements of red and infrared light.

In another aspect, the invention is apparatus for measuring oxygen saturation which includes:

means for repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit,

means for repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit,

means for repeatedly calculating hematocrit level in the blood as it passes through the blood circuit based on the infrared measurement, and

means for repeatedly determining oxygen saturation in the blood based on the above measurements and the hematocrit calculation, and selecting a different formula for the determination according to the level of oxygen saturation.

Preferably, the apparatus in this aspect includes means for selecting the oxygen saturation formula according to the hematocrit level as well. The hematocrit calculation is usually made using an approximation or representation of the amount of light reflected at the isobestic wavelength, and, in certain embodiments, is made using an actual measurement of the amount of light reflected at the isobestic wavelength.

In yet another aspect, the invention is apparatus for determining oxygen saturation in blood in a blood circuit. The apparatus includes:

means for repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit,

means for repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit, and

means for repeatedly calculating oxygen saturation in the blood based on the measurements, using a different formula for the determination of oxygen saturation according to the level of hematocrit in the blood.

Preferably, the apparatus in this aspect also includes means for repeatedly calculating hematocrit level of the blood as it passes through the circuit and the means for calculating oxygen saturation includes means for correcting the oxygen saturation calculation for the hematocrit level. The means for calculating hematocrit includes a means for approximating the amount of reflected light at the isobestic wavelength of deoxy- and oxyhemoglobin.

In all the above apparati, the means for providing light are preferably light-emitting diodes, the means for measuring the amount of light is a photodiode, and the means for calculating is software. Generally, the blood is passed through a cuvette and the diodes provide and receive light through fiber-optic cables, the emitting cables being equidistant from the receiving cables at the blood or cuvette interface. In

general, the LEDs emit light sequentially and a central processing unit controls the apparatus.

Preferably the wavelength of the infrared light is either at about the isobestic wavelength of oxy- and deoxyhemoglobin, or is at two wavelengths symmetrically disposed about the isobestic wavelength, most preferably at 810 and 830 nm. In the latter case, the software provides one of the above-mentioned two formulas for approximating or representing the amount of reflected light at the isobestic point.

The software also provides specific formulas for the calculations of oxygen saturation and hematocrit in the preferred embodiment of these aspects of the invention. Two formulas for the calculation of oxygen saturation and for hematocrit are mentioned above.

In the above aspects, as well as in other aspects, the present invention provides an advantageous method and apparatus for determining oxygen saturation which avoids problems associated with various prior methods and devices.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an overall illustration of the entire apparatus.

Fig. 2A is a plan view of the end of the fiber-optic cable where it attaches to the cuvette. Fig. 2B is a longitudinal cross-section of the cuvette attached to the cable.

Fig. 3A is a cross section of the bulkhead connector between the cable and the instrument. Fig. 3B is an enlargement of the area where the fiber-optic channels connect and Figs. 3C and 3D are isometric end views of the two parts of the bulkhead connector.

Fig. 4A is a longitudinal cross-section of the cuvette. Fig. 4B is a cross-section of the cuvette taken at lines 4B-4B of Fig. 4A. Fig 4C is a top view of the cuvette and window. Fig. 4D is a cross-section of the calibration cuvette.

Fig. 5A is a cross-section of the lock or latch mechanism attaching the cuvette to the main cable; Figs. 5B and 5C are enlargements. Fig. 5D is a side elevation of the latch mechanism.

Figs. 6A and 6B form a system block diagram for the apparatus.

Figs. 7A and 7B are flow charts, respectively, of the software for the "Calibrate" mode and the "Run" mode.

Figs. 8A and 8B are tables of partitioned equations for the determination of oxygen saturation. Fig. 8C is a flow chart

of software performing the oxygen determinations using the partitioned equations of Fig. 8A, and Fig. 8D is a flow chart of software using the partitioned equations of Fig. 8B.

Fig. 9 is a graph of the reflection curves of deoxygenated and oxygenated hemoglobin showing the isobestic point.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present method of determining oxygen saturation is accomplished using the oximetric device described here.

I. Overall Fiber-optic Sensor System

The preferred embodiment of the system 1 shown in Fig. 1 includes an instrument or electronic module 3 housing LEDs, photodetectors, and hardware and software. Two non-disposable fiber-optic cables 5 and two cuvettes 7a and 7b, which are placed in the blood stream path, are included so that oxygen saturation and hematocrit in blood passing through the cuvettes in the extracorporeal blood circuit can be measured. A printer (not shown) can be attached to the module or housing 3. One cuvette 7a is located in the venous flow path and one, 7b, is located in the arterial flow path, so oxygen saturation and hematocrit of both can be monitored and displayed. The device is physically and operationally identical for both the arterial and venous paths, except where indicated below;

therefore only one of the two paths is described below unless specific description of the other path is necessary.

II. Fiber-optic Cable

Referring to Figs. 2A and 2B, the preferred cable 5 includes four fiber-optic channels. The fiber-optic channels are formed of polymethyl methacrylate with fluorinated polymer cladding obtained from PolyOptical Products, Inc., Santa Ana, California. One is an emitter channel 10 for transmitting 660 nm radiation from a 660 nm LED (20 in Fig. 6A) to the blood sample; a second is an emitter channel 12 transmitting 810 nm infrared radiation from an 810 nm LED (22 in Fig. 6A) in module 3, to the blood sample; a third is an emitter channel 14 transmitting 830 nm IR radiation from an 830 nm LED (24 in Fig. 6A) in module 3 to the blood sample. A single LED at the true isobestic wavelength (about 820 nm) and a single corresponding channel can be chosen, if available, to avoid the need for both the 810 and 830 nm channels. These emitter channels transmit the radiation through the window of the cuvette 7, discussed below, to the blood sample, illuminating the blood.

The fiber-optic cable 5 also includes a fourth channel 16 for receiving reflected radiation at the input wavelengths, and transmitting it to a signal photodetector 258 (shown in Fig. 6A) in the electronic module. This preferred embodiment measures reflected light, as indicated, but it is within the

scope of the invention to measure transmitted light instead, in the case of an appropriate device.

At the distal end of the cable, the fiber-optic channels are spaced with the emitter channels equidistant from detector channel 16, as shown in Fig. 2A. The preferred fiber-optic channel size for all the emitter channels is .030 inches in diameter, the detector channel is preferably .040 inches in diameter and the emitter channels are preferably located about .047 inches from detector channel 16. For a particular device, the distance of the emitter channels from the detector channel at the blood interface can be optimized using methods known in the art.

III. Bulkhead Connector

The proximal end of the cable is attached to instrument 3 via a bulkhead attachment 30 shown in cross-section in Figs. 1 and 3A, and in 3B and 3C. A round female unit 32 having interior threads 34 and a key 36 is rotatable with respect to the cable. A male unit 38 with threads 31, mounting unit 7 for mounting in housing 3, and key slot 35 is disposed in module 3.

To connect the cable to the module, the male unit is placed within the female unit, key slot to key, and the female unit 32 is rotated to attach the cables to the bulkhead, companion fiber-optic channels not more than .010 inches apart from each

other. An enlargement of the connection is shown in Fig. 3B, with a small space 33 between the companion channels.

IV. Cuvette

A cuvette 7a or 7b shown in Figs. 2B, 4A, 4B, and 4C is placed within the extracorporeal blood path for blood flow therethrough during bypass surgery. The blood flows longitudinally through the cuvette through axial cavity 50. The cuvette is molded of polycarbonate for convenient light transmission and is of generally cylindrical shape. Barbed fittings 51 at each end are designed to fit within the tubing of the extracorporeal circuit with a leak-free seal.

V. Latch Connector

When in use, the cuvette is attached to the cable via lock or latch 70 shown in Figs. 2A-B. On cable 5, the lock includes knob 72 rotatable with respect to foot 73 containing the fiber-optic channels. Foot 73 has stops 74 and 76 which limit rotation of knob 72 when they contact extensions 78 and 80. Springs 81 bias foot 73 away from cable 5. Stops 74 and 76 contain key slots or channels 82 and 84, preferably of different sizes. Extensions 78 and 80 together with stops 74 and 76 define an area of rotation of knob 72; the knob can be rotated so that the key slots are located at a position A or a position B as shown. Adjacent the key slots when they are located in position B are lips 86 and 88, each with its own stop 90 and raised lock 92.

Cuvette 7 contains keys 94 and 96, each designed to be received in one of slots 82 or 84; space 95 between them is designed to receive foot 72. Each key defines an aperture 98 and flange 97 which can receive a lip 86 or 88.

The cuvette is attached to the cable by sliding the keys into the appropriate key slots when knob 72 is in position A. Cuvette 7 and foot 73 are then urged toward the cable and the knob rotated so that cuvette flanges 97 pass over locks 92 and reach stops 90 with the knob in position B. Pressure on the cuvette and foot is then released and spring 81 in cooperation with locks 92 firmly hold the channel and cuvette in place with channels 10, 12, 14, 16 abutting window 52 of the cuvette.

VI. System Block Diagram

A system block diagram for the entire device is shown in Figs. 6A and 6B. Bulkhead connector 30 contains three optical channels 250, 252, and 254 to conduct LED illumination to the bulkhead. It also contains one optical channel 256 to conduct reflected signal energy to the signal detector 258 and one optical channel 260 to conduct disconnect signal energy to the disconnect detector 262.

Signal detector 258 is connected to the signal detector amplifier 264 that amplifies the signal in a range usable for

the analog-to-digital converter 266. The analog-to-digital converter data is fed to the CPU 270.

Optical channels 250, 252, and 254 are coupled to individual LEDs 20, 22 and 24 of the three wavelengths 660 nm, 810 nm, and 830 nm, respectively. Each LED is energized by its LED driver, shown as one of 274a, b, or c on Fig. 6A. Each LED driver is individually turned on and off by the CPU.

The intensity of each LED is controlled by an individual compensation circuit. Each compensation circuit consists of a compensator detector, one of 276a, b, or c to monitor the LED energy. Each compensator detector is coupled to a compensator detector amplifier, one of 278a, b, or c, which amplifies the signal. Each compensator detector amplifier signal is coupled via a multiplexer, a comparator-integrator and another multiplexer to the appropriate LED driver 274a, b, or c. If the LED energy varies from its set point, this information is fed to the LED driver and the LED driver adjusts the LED energy as necessary to maintain the set point.

In operation, individual LED energies are sequentially triggered to illuminate the sample via cable 5. The reflected energy from the sample is transmitted through the detector channel 16 in cable 5 to the signal detector 258. The signal is amplified by the signal detector amplifier 264, converted to digital data via the analog digital converter 266, and read

by CPU 270. Preferably, the individual LEDs are triggered so that the detector reads first the "ambient" light received along the channel and then reads the reflected light at the LED wavelength. The "ambient" data is subtracted from the reflected data in the software before correction for calibration.

Referring now to Fig. 6B, the CPU 270 is a standard 8-bit micro-controller with RAM 280, ROM 282, a watch dog timer 284, and an asynchronous serial port 286 for attachment to printer 2 in this case. Additional system components are the power supply 288, an LCD display 290, a test switch 292 and an event switch 294 all connected to the CPU.

VII. Software

A. Calibration

When the device is first used, it is calibrated to compensate for variations in the individual system's optical components; by taking measurements under known conditions, normalization factors can be determined for each LED emitter channel and detector channel combinations. Such factors are developed to correct the raw readings at each channel for variations inherent in each system.

Calibration is accomplished in the preferred embodiment using a calibration cuvette 500 shown in Fig. 4D. This is a cuvette designed to be attached to the cable unit in the same fashion

as a standard cuvette. However, it contains a material designed to provide a known amount of reflected light in the device at the selected wavelengths.

The calibration cuvette does not contain a chamber for blood passage; instead, it contains a well 502 to contain reflective material 504. Preferably, for simplicity of manufacture, it otherwise duplicates the standard cuvette as much as possible. Also, it terminates in two bases 506 and 508 which are permanently adhesively attached to the instrument module 3 for convenience of use for each calibration. Material 504 is designed to resemble blood in that the amount of light reflected is similar to that of blood. Since the preferred device is designed to operate maximally with blood giving a signal of about 2.0 to 3.0 volts, the preferred calibration standard gives a signal in this range also.

In an attempt to maximize accuracy of the calibration, the device is preferably calibrated using a calibration standard (material 504) providing a voltage just above the maximum reflected voltage level for blood. Using as high a voltage as possible within the desired level minimizes the effect of errors in the calibration reading on the normalization factors which calibration creates. The maximum voltage read from blood in the preferred embodiment at the 660 nm wavelength is about 2.8 volts while the maximum at the 810 and 830 nm wavelengths is about 2.5 volts. In the preferred embodiment,

thus, the calibration standard reflects at a level equivalent to 3.0 volts on the 660 nm channel and 2.5 volts on the 810 and 830 nm channels.

The material used for the calibration includes a light-scattering agent dispersed at desired levels in a support medium. The support matrix is substantially non-light-absorbing at the wavelengths of interest and may be formed of a number of materials such as silicone elastomers (like Dow Corning's Silastic MDX 4-4210), urethanes, epoxy, or other materials. The support matrix is generally chosen for certain characteristics. Specifically, it should cure to a solid fairly quickly without allowing the dispersed materials to settle out. Once cured, its viscosity and other features should be stable over time. The preferred support matrix is epoxy which shows limited degradation over time.

A number of light-scattering materials can be used such as titanium dioxide, Tempera paint pigment, silicon carbide, ferric oxide, etc., which can be evenly dispersed in the matrix. These materials should be generally non-varying over time and, if possible, of a uniform particle size.

In some embodiments, dyes may be used to diminish the reflected light at certain wavelengths. These dyes may be included in the support matrix or may be independently

dispersed. Some possible dyes are Pro-Jet 830, a blue pigment dispersion made by Huls Petrarch, Inc., or Thymol blue made by Fisher Chemical Company. The blue dyes will reduce the amount of reflected red light.

The preferred material, specifically, will include about:

59.4% by weight	Epoxy resin
35.6% by weight	Epoxy hardener
5.0% by weight	Titanium dioxide powder

The preferred epoxy is Hexcel Epolite 3310, a 75 Shore D clear epoxy.

The preferred titanium dioxide (or Titanium (IV) Oxide) is a white powder of greater than 99.9% purity in the anatase form.

The mixture is cured in the cavity 502 of calibration cuvette 500 shown in Fig. 4D and is preferably about 1/4 inch thick, or at least thick enough and sufficiently opaque so that ambient light does not enter from the rear.

The calibration constants in the preferred device, 3.0 volts for the 660 nm channel, 2.5 volts on the 810 channel, and 2.5 volts on the 830 nm channel are used to calculate normalization factors as follows:

$$\text{Normalization factor} = \frac{\text{Constant for wavelength}}{\text{Reflected light at wavelength during calibration}}$$

For example, if the voltage read on the 660 channel using the standard is 2.9, the normalization factor for that channel is:

$$\text{Normalization factor} = \frac{\text{Constant}_{660}}{\text{Voltage}} = \frac{3.0}{2.9} = 1.03$$

If, for example, on the other two channels, the voltage on the 810 nm channel during calibration is 2.4 and that on the 830 channel is 2.3, the normalization factor for each will be:

$$\text{Normalization factor}_{810} = \frac{\text{Constant}_{810}}{\text{Voltage}} = \frac{2.5}{2.4} = 1.04$$

and

$$\text{Normalization factor}_{830} = \frac{\text{Constant}_{830}}{\text{Voltage}} = \frac{2.5}{2.3} = 1.09$$

These factors are stored in RAM as the normalization factors for each channel, and thus readings on each channel are separately calibrated and corrected for variability of the system.

A software flow diagram for the calibration process is shown in Fig. 7A.

The CPU first displays "Cal" in the arterial and venous windows 292 to prompt the operator to depress the Test switch

290, [redacted] waits for the switch to be [redacted]eld for at least 3 seconds, steps 300, 302 in Fig. 7A. The LED drivers are then directed to energize the LEDs sequentially, step 304.

Data is acquired on the venous and arterial channels at each wavelength as follows. Detector voltages are captured for each wavelength on the venous channel in the hardware capture circuitry described previously. Each captured venous voltage is digitized and stored in RAM in the venous data table, step 304. The same steps are taken for the arterial channel, step 350.

Normalization factors are calculated for each wavelength by the CPU using the acquired data, steps 308, 352. Raw data and the normalization factors are then compared to preset limits for validation, steps 306, 310, 350, 354. If either channel is found to be invalid, the CPU blanks the display. If both channels are invalid, a "Fail" flag is set (and displayed), the "Cal" flag is redisplayed and the procedure must be restarted, steps 314, 358, or problems with the device corrected.

If the venous channel data and normalization factor are found to be valid, an active channel flag is set; the same is done for the arterial channel, step 356. A "Pass" flag is then set and displayed, step 360. If one of the channels is invalid, its display window is blanked.

In use, the CPU uses the normalization factors for each channel to correct raw readings before calculating hematocrit and oxygen saturation via software contained in RAM.

B. Run Mode

After calibration, the device operates in the "Run" mode. All variables, flags and registers are initialized for the run mode and normalization factors are included. The run mode is the normal operational mode for the instrument that is active until the device is powered down. An itemization of one run mode cycle after initial testing (step 400, as described above) is then shown in Fig. 7B.

The detector voltages are captured and processed as described in the calibration section above, steps 402, 404, 450, 452. The output is the venous data table which contains values for each wavelength and the arterial data table, which also contains output for each wavelength.

The venous data is processed as follows. If the venous channel is not active, the procedure is exited, 402, and arterial procedure entered. If active, the venous channel data is compared to acceptable limits, 406. If the venous data is not valid, an error message is displayed in the venous display window, 414, and the procedure is exited. If valid, the data (which has already been corrected for ambient signals) is adjusted for VCO non-linearities.

Finally the data for each channel is then normalized, using the normalization factors obtained in the calibration mode. This is done by multiplying the received data by the multiplicative scale factor determined during calibration. For example, in the example shown, the received data on the 660 channel will be multiplied by 1.03, on the 810 channel by 1.04, and on the 830 channel by 1.09. Calculation of hematocrit and then oxygen saturation is then completed as described later using the normalized data.

Venous saturation results produced as described above are then displayed, 410, 412. Arterial channel data is similarly processed, steps 462-462, but venous hematocrit is displayed, 416, if the channel is inactive. Otherwise, arterial saturation and hematocrit are displayed, 460. A printer can be used if desired, see 464-468.

VIII. DETERMINATION OF HEMATOCRIT AND OXYGEN SATURATION

A. Hematocrit

Where an LED is used which actually produces a wavelength at the isobestic point (about 820 nm) for hemoglobin and deoxyhemoglobin, that measurement is used in the calculation of hematocrit. Specifically, using the normalized data, a

reflectance measurement $R_{ISOBESTIC}$ OR R_I is obtained, as follows for use in the measurement of hematocrit:

$$R_I = R_{820}$$

Otherwise, LEDs generating wavelengths symmetrically disposed about the isobestic point on the oxy-deoxyhemoglobin curve can be used to generate a representation of the amount of light reflected at the isobestic point. As can be seen on Fig. 9, if an LED generating the exact isobestic wavelength is not available in the device, two LEDs generating wavelengths disposed on either side of the isobestic point can be used[1]. The difference between the two curves at the one wavelength should be equal but opposite to the difference between the two curves at the other wavelength.

For example, in the preferred embodiment, LEDs generating wavelengths of 810 nm and 830 nm can be used, although other wavelengths such as 800 and 840 nm can be used. $R_{ISOBESTIC}$ or R_I can then be represented or approximated as follows:

$$R_I = \frac{R_{FIRST\ INFRARED} + R_{SECOND\ INFRARED}}{2}$$

or

$$R_I = R_{FIRST\ INFRARED} \times R_{SECOND\ INFRARED}$$

In the preferred embodiment, then

$$R_I = \left(\frac{R_{810} + R_{830}}{2} \right) \text{ or } \left(R_{810} \times R_{830} \right),$$

[1]It should be noted that LEDs used should be screened to determine actual wavelengths emitted, since the actual may not be the same as the labeled wavelength.

Hematocrit (Hct) can then be calculated by using the R_I value:

$$\%Hct = A \cdot R_I + B \cdot (R_I^2) + \frac{C}{R_I} + \frac{D}{R_I^2}$$

This equation, including constants A, B, C and D, was empirically derived by comparing R_I values and their associated known hematocrit values, and is believed to provide very accurate measurements. In the preferred embodiment, the constants have been found to be as follows, using the first equation for R_I provided above. Where the second equation for R_I is used, a different set of constants must be generated, as is the case when R_I is measured directly, using a wavelength at about the actual isobestic point on the curve.

A = 19.670148

B = 6.833192

C = 9.833347

D = 0.8262

Under abnormal physiological conditions (such as very unusual flow rates, pH, etc.), it may be desirable to use a modified equation which is believed to be more accurate under such conditions, e.g.:

$$Hct = Exp\left(L \cdot R_I + \frac{M}{Ln(R_I^2)}\right)$$

This equation was developed by including such abnormal test data while generating the hematocrit calculation formula. L and M are constants generated for the device.

B. Oxygen Saturation

Oxygen saturation is determined using a $Ratio_O$ where:

$$R_0 = R_{INFRARED} \times R_{RED}$$

Specifically, here:

$$Ratio_O = \frac{R_{830}}{R_{660}}$$

If an actual isobestic wavelength is used instead of the 830 nm LED, then

$$Ratio_O = \frac{R_{ISOBESTIC}}{R_{660}}$$

Oxygen saturation is then calculated as follows, where Hct is the hematocrit value determined above:

$$\%sO_2 = E \cdot Ratio_O + \frac{F}{Ratio_O} + \frac{G}{Ratio_O^2} + H \cdot \frac{Ratio_O}{Hct} + I \cdot Hct + \frac{J}{Hct} + \frac{K}{Hct^2}$$

E through K are constants determined for the device before manufacture by comparing data from numerous such test devices to actual oxygen saturation figures.

Specifically, in the device shown,

E = 3.462727

F = 36.690131

G = 7.060379

H = 500.693864

I = 0.570215

J = 1425.89362

K = 7708.556902

Different constants will be generated where $R_{ISOBESTIC}$ is used rather than R_{830}.

This approach is believed to provide particularly accurate oxygen saturation data. Not only is the oxygen saturation data corrected for hematocrit variations, but it is also corrected for hematocrit which is measured essentially instantaneously. Furthermore, hematocrit is believed to be calculated very accurately via such actual or approximated reflectance at the isobestic point. Thus, variations in, and errors in the calculation of, the hematocrit level during a bypass procedure does not result in erroneous saturation readings.

Again, to avoid error under abnormal physiological conditions in some embodiments, the following modified calculation of oxygen saturation can be used:

$$sO_2 = N \cdot Ratio_O + O/Ratio_O + P/(Ratio_O^2) + Q \cdot Ratio_O/Hct + S \cdot Hct + T \cdot Ln(Hct)$$

Determining sO_2 in this fashion is believed to reduce sO_2 error, particularly under abnormal conditions. N through T are constants determined for the individual device.

It was found possible to optimize the calculation of oxygen saturation by partitioning the response curves of the device and including abnormal values. Partitioning was done by both sO_2 level and by hematocrit level to give sixteen formulas, four sO_2 ranges in each of four hematocrit ranges. Partitioning only by hematocrit level provided four formulas. Fig. 8A contains sixteen particular equations found optimum for the calculation of sO_2 in the preferred embodiment, partitioning by both Hct and sO_2, when used in connection with bovine blood; Fig. 8B lists the four particular equations found optimum when hematocrit levels alone were used. Levels of hematocrit and sO_2 as referred to in the Figures are as follows:

High Hct (level 1)	= 33 - 40%
Medium high Hct (level 2)	= 26 - 33%
Medium low Hct (level 3)	= 21 - 26%
Low Hct (level 4)	= 14 - 21%
High sO_2	= 90 - 100%
Medium high sO_2	= 70 - 90%
Medium low sO_2	= 50 - 70%
Low sO_2	= 30 - 50%

Software for incorporating the formulas of Figs. 8A and 8B in the device can be prepared by one of ordinary skill in the art. Sample flow charts, however, for such software are provided in Figs. 8C and 8D. It should be noted that in actually utilizing these equations, $Ratio_0$ is used as an estimate of sO_2 rather than the fully-calculated sO_2 value.

Also, [redacted] the figures (and the claim[redacted] $Ratio_0$ is sometimes referred to as "Ratio" or "Rat."

This approach is believed to further improve the accuracy of the sO_2 determination, as indicated by a reduction in the standard deviation of the bias with the 4-block partition and a further reduction with the 16-block approach. (Data shows the reduction to be from 2.2 to 1.2 to 1.0.)

IX. Use of the Device

The device is first assembled before use, the second cable unit attached to the instrument using the bulkhead attachment and the cuvettes placed in what will be the extracorporeal circuit after it is primed. The cables are attached to the cuvettes using the latches. The device is then calibrated using the calibration cell provided, before priming.

Once the system has been primed and is running, the device can be used to measure hematocrit and oxygen saturation. Using the equations set forth above, the device displays hematocrit readings and oxygen saturation readings. A printer can be activated to print readings if desired. Once the surgery is completed, the cuvette is removed from the circuit and disposed of, and the device readied for another use, with another cuvette, following the procedures described above.

It will be understood that the above description and the illustrations are provided by way of example only, that alternate versions, equivalents, and examples will be apparent to those skilled in the art, and will be within the scope of the invention which is defined by the appended claims. For example, transmitted rather than reflected light can be measured with certain devices.

WHAT IS CLAIMED IS:

1. A method of determining oxygen saturation in blood passing through a blood circuit comprising the following steps:

a) providing light to the blood as it passes through the blood circuit;

b) receiving light reflected from the blood at a given distance from the provided light;

c) utilizing the received light to make an approximation of the amount of light reflected from the blood at the isobestic wavelength of oxy- and deoxyhemoglobin;

d) calculating the hematocrit level of the blood passing through the blood circuit using the determination of step c); and e) calculating oxygen saturation in the blood passing through the blood circuit based on the amount of light reflected from the blood and the calculation made in step d) so that the oxygen saturation determination includes a correction for the hematocrit level of the blood passing through the circuit, calculated according to the amount of light reflected at the isobestic wavelength of oxy- and deoxyhemoglobin.

2. A method of determining oxygen saturation in blood in a blood circuit according to claim 1 further comprising the following steps:

f) repeatedly providing light to the blood at a wavelength in the red range;

g) repeatedly providing the light of step a) at a wavelength in the infrared range;

h) repeatedly measuring the amount of the red light reflected from blood, as the blood passes through the blood circuit;

i) repeatedly measuring the infrared light reflected from blood as the blood passes through the blood circuit; and

j) calculating oxygen saturation based on the results of steps e) and i).

3. A method according to claim 2 and wherein the wavelength of the infrared radiation is at about the isobestic point of oxy- and deoxyhemoglobin so that the measurement of step i) can be used as the approximation of step c).

4. A method according to claim 2 and further including the steps of k) repeatedly providing light at a second infrared wavelength to the blood and l) repeatedly measuring the amount of the second infrared wavelength reflected from the blood at a single distance from the light provided, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic point.

5. A method according to claim 4 and wherein the determination of oxygen saturation includes the step of calculating the ratio of the measurement of step i) to the measurement of step h).

6. A method according to claim 2 and wherein different formulas are used in the determination of oxygen saturation according to the hematocrit level.

7. A method according to claim 2 and wherein different formulas are used for the determination of oxygen saturation according to the oxygen saturation level.

8. A method of determining oxygen saturation of blood in a blood circuit comprising the following steps:

a) repeatedly measuring light at a wavelength in the red range of the blood as it passes through the blood circuit;

b) repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit;

c) repeatedly calculating hematocrit level in the blood as it passes through the blood circuit based on the measurements of step b);

d) repeatedly determining oxygen saturation in the blood based on the measurements of steps a), b) and c), using more than one different formula for the determination, depending on the level of oxygen saturation.

9. A method according to claim 8 further comprising the following steps

e) repeatedly providing red light to the blood;

f) repeatedly providing infrared light to the blood

and wherein the formula is selected according to the hematocrit level.

10. A method according to claim 9 and wherein the wavelength in the infrared range is at the isobestic point on the reflection curves of deoxy- and oxyhemoglobin, so that the measurement of step b is used as the approximation of the amount of light reflected at the isobestic point.

11. A method according to claim 9 and further including the steps of repeatedly providing light at a second infrared wavelength to the blood and repeatedly measuring the amount of the second infrared wavelength reflected from the blood, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic point.

12. A method according to claim 9 and wherein the determination of oxygen saturation includes the step of calculating the ratio of the measurement of step b) to the measurement of step a).

13. A method of determining oxygen saturation in blood in a blood circuit comprising the following steps:

a) repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit;

b) repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit;

c) repeatedly calculating oxygen saturation in the blood based on the measurements taken in steps a) and b), using a different formula for the determination of oxygen saturation depending on the level of hematocrit in the blood.

14. A method according to claim 13 and further including a step d) of repeatedly calculating hematocrit level in the blood as it passes through the blood circuit e) of repeatedly providing red light to the blood, and f) of repeatedly providing infrared light to the blood, and wherein the calculation of oxygen saturation is based on the measurements taken in steps a) and, b), and the calculation of step d), so that the oxygen saturation calculation includes a correction for the hematocrit level of the blood passing through the circuit.

15. A method according to claim 14 and wherein the calculation of hematocrit is based on the measurement of step b) only.

16. A method according to claim 15 and wherein hematocrit is determined using a calculation based on an approximation of the amount of reflected light at the isobestic point on the reflection curves of deoxy and oxyhemoglobin.

17. A method according to claim 16 and further including the steps g) of repeatedly providing light at a second infrared wavelength to the blood and h) repeatedly measuring the amount of the second infrared wavelength reflected from the blood, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic point.

18. A method according to claim 4, 11, and 17 and wherein the approximation of the amount of light reflected at the isobestic point is made according to the following formula, where R represents the amount of reflected light at the specified wavelength:

$$R_{ISOBESTIC} = \frac{R_{FIRST\ INFRARED} + R_{SECOND\ INFRARED}}{2}$$

19. A method according to claim 4, 11, and 17 and wherein the approximation of the amount of light reflected at the isobestic point is made according to the following formula, where R represents the amount of reflected light at the specified wavelength:

$$R_{ISOBESTIC} = R_{FIRST\ INFRARED} \times R_{SECOND\ INFRARED}$$

20. A method according to claim 2, 9 or 13 and wherein hematocrit is determined using the following formula, where A, B, C, and D are constants and $R_{ISOBESTIC}$ represents the amount of light reflected from the blood at the isobestic point on the reflection curve of oxy- and deoxyhemoglobin:

$$Hct = A \cdot R_{ISOBESTIC} + B \cdot R_{ISOBESTIC}^2 + \frac{C}{R_{ISOBESTIC}} + \frac{D}{R_{ISOBESTIC}^2}$$

21. A method according to claim 2, 9 or 13 and wherein hematocrit is determined using the following formula, where L and M are constants and $R_{ISOBESTIC}$ represents the amount of light reflected from the blood at the isobestic wavelength:

$$Hct = Exp\left(L \cdot R_{ISOBESTIC} + \frac{M}{Ln(R_{ISOBESTIC}^2)} \right)$$

22. A method according to claims 2, 9 or 15 and wherein the wavelength of the red radiation is at about 660 nm.

23. A method according to claims 4, 11, or 17 and wherein the first infrared wavelength is about 810 nm and the second infrared wavelength is about 830 nm.

24. A method according to claim 15 and wherein the determination of oxygen saturation includes the step of calculating the ratio of the measurement of step b) to the measurement of step a).

25. A method according to claim 24 and wherein different formulas are used in the calculation of oxygen saturation according to the hematocrit level.

26. A method according to claim 9 or 16 and wherein for a given hematocrit range, the oxygen saturation formula is selected according to the level of oxygen saturation from the following group of formulas, where A_1, B_1, C_1, D_1, A_2, B_2, C_2, A_3, B_3, C_3, D_3, A_4, B_4, C_4 and D_4 are constants, and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_1 \cdot Ratio + \frac{B_1}{Ratio} + C_1 \cdot (Ratio^2) + D_1 \cdot Ln(Hct)$$

$$A_3 \cdot Ratio + \frac{B_3}{Ratio} + \frac{C_3}{Ratio^2} + D_3 \cdot Ln(Hct)$$

$$\frac{A_2}{Ratio} + \frac{B_2}{Ratio^2} + C_2 \cdot Ln(Hct)$$

and

$$A_4 \cdot Ratio + \frac{B_4}{Ratio_0} + \frac{C_4}{Ratio^2} + D_4 \cdot Ln(Hct)$$

27. A method according to claim 9 or 16 and wherein for a given hematocrit range, the oxygen saturation formula is selected according to the level of oxygen saturation from the following group of formulas, where A_5, B_5, C_5, D_5, A_6, B_6, C_6, D_6, A_7, B_7, C_7, D_7, A_8, B_8, C_8, and D_8 are constants, and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_5 \cdot Ratio + \frac{B_5}{Ratio} + \frac{C_5}{Ratio^2} + D_5 \cdot Ln(Hct)$$

$$A_7 \cdot Ratio + \frac{B_7}{Ratio} + C_7 \cdot Ln(Hct) + D_7 \cdot \frac{Hct}{Ratio}$$

$$A_6 \cdot Ratio + \frac{B_6}{Ratio} + \frac{C_6}{Ratio^2} + \frac{D_6}{Hct}$$

and

$$A_8 \cdot Ratio + \frac{B_8}{Ratio} + \frac{C_8}{Ratio^2} + D_8 \cdot Ln(Hct)$$

28. A method according to claim 9 or 16 and wherein for a given hematocrit range, the oxygen saturation formula is selected according to the level of oxygen saturation from the following group of formulas, where A_9, B_9, C_9, D_9, A_{10}, B_{10}, C_{10}, D_{10}, E_{10}, A_{11}, B_{11}, C_{11}, D_{11}, A_{12}, B_{12}, C_{12}, and D_{12} are constants, and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_9 \cdot Ratio + \frac{B_9}{Ratio} + \frac{C_9}{Ratio^2} + D_9 \cdot \frac{Ratio}{Hct}$$

$$A_{11} \cdot Ratio + \frac{B_{11}}{Ratio} + C_{11} \cdot Ln(Hct) + D_{11} \cdot \frac{Hct}{Ratio}$$

$$A_{10} \cdot Ratio + \frac{B_{10}}{Ratio} + \frac{C_{10}}{Ratio^2} + D_{10} \cdot Ln(Hct) + E_{10} \cdot \frac{Hct}{Ratio}$$

and

$$A_{12} \cdot Ratio + \frac{B_{12}}{Ratio} + \frac{C_{12}}{Ratio^2} + D_{12} \cdot Ln(Hct)$$

29. A method according to claim 9 or 16 and wherein for a given hematocrit range, the oxygen saturation formula is selected according to the level of oxygen saturation from the following group of formulas, where A_{13}, B_{13}, C_{13}, D_{13}, A_{14}, B_{14}, C_{14}, D_{14}, A_{15}, B_{15}, C_{15}, D_{15}, A_{16}, B_{16}, and C_{16} are constants, and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_{13} \cdot Ratio + \frac{B_{13}}{Ratio} + \frac{C_{13}}{Ratio^2} + D_{13} \cdot \frac{Ratio}{Hct}$$

$$A_{15} \cdot Ratio + \frac{B_{15}}{Ratio} + C_{15} \cdot Ln(Hct) + D_{15} \cdot \frac{Hct}{Ratio}$$

$$A_{14} \cdot Ratio + \frac{B_{14}}{Ratio} + \frac{C_{14}}{Ratio^2} + \frac{D_{14}}{Hct}$$

and

$$\frac{A_{16}}{Ratio} + \frac{B_{16}}{Ratio^2} + C_{16} \cdot Ln(Hct)$$

30. A method according to claim 9 or 16 and wherein for a given oxygen saturation range, the oxygen saturation formula is selected according to the level of hematocrit, where A_1, B_1, C_1, D_1, A_5, B_5, C_5, D_5, A_9, B_9, C_9, D_9, A_{13}, B_{13}, C_{13} and D_{13} are constants and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_1 \cdot Ratio + \frac{B_1}{Ratio} + C_1 \cdot (Ratio^2) + D_1 \cdot Ln(Hct)$$

$$A_5 \cdot Ratio + \frac{B_5}{Ratio} + \frac{C_5}{Ratio^2} + D_5 \cdot Ln(Hct)$$

$$A_9 \cdot Ratio + \frac{B_9}{Ratio} + \frac{C_9}{Ratio^2} + D_9 \cdot \frac{Ratio}{Hct}$$

and

$$A_{13} \cdot Ratio + \frac{B_{13}}{Ratio} + \frac{C_{13}}{Ratio^2} + D_{13} \cdot \frac{Ratio}{Hct}$$

31. A method according to claim 9 or 16 and wherein for a given oxygen saturation range, the oxygen saturation formula is selected according to the level of hematocrit, where A_3, B_3, C_3, D_3, A_7, B_7, C_7, D_7, A_{11}, B_{11}, C_{11}, D_{11}, A_{15}, B_{15}, C_{15} and D_{15} are constants and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_3 \cdot Ratio + \frac{B_3}{Ratio} + \frac{C_3}{Ratio^2} + D_3 \cdot Ln(Hct)$$

$$A_7 \cdot Ratio + \frac{B_7}{Ratio} + C_7 \cdot Ln(Hct) + D_7 \cdot \frac{Hct}{Ratio}$$

$$A_{11}\cdot Ratio + \frac{B_{11}}{Ratio} + C_{11}\cdot Ln(Hct) + D_{11}\cdot \frac{Hct}{Ratio}$$

and

$$A_{15}\cdot Ratio + \frac{B_{15}}{Ratio} + C_{15}\cdot Ln(Hct) + D_{15}\cdot \frac{Hct}{Ratio}$$

32. A method according to claim 9 or 16 and wherein for a given oxygen saturation range, the oxygen saturation formula is selected according to the level of hematocrit, where A_2, B_2, C_2, A_6, B_6, C_6, D_6, A_{10}, B_{10}, C_{10}, D_{10}, A_{16}, B_{16}, and C_{16} are constants and Ratio is the ratio of the infrared measurement to the red measurement:

$$\frac{A_2}{Ratio} + \frac{B_2}{Ratio^2} + C_2\cdot Ln(Hct)$$

$$A_6\cdot Ratio + \frac{B_6}{Ratio} + \frac{C_6}{Ratio^2} + \frac{D_6}{Hct}$$

$$A_{10}\cdot Ratio + \frac{B_{10}}{Ratio} + \frac{C_{10}}{Ratio^2} + D_{10}\cdot Ln(Hct) + E_{10}\cdot \frac{Hct}{Ratio}$$

and

$$\frac{A_{16}}{Ratio} + \frac{B_{16}}{Ratio^2} + C_{16}\cdot Ln(Hct)$$

33. A method according to claim 9 or 16 and wherein for a given oxygen saturation range, the oxygen saturation formula is selected according to the level of hematocrit, where A_4, B_4, C_4, D_4, A_8, B_8, C_8, D_8, A_{12}, B_{12}, C_{12}, D_{12}, A_{14}, B_{14}, C_{16} and D_{16} are constants and Ratio is the ratio of the infrared measurement to the red measurement:

$$A_4\cdot Ratio + \frac{B_4}{Ratio_0} + \frac{C_4}{Ratio^2} + D_4\cdot Ln(Hct)$$

$$A_8 \cdot Ratio + \frac{B_8}{Ratio} + \frac{C_8}{Ratio^2} + D_8 \cdot Ln(Hct)$$

$$A_{12} \cdot Ratio + \frac{B_{12}}{Ratio} + \frac{C_{12}}{Ratio^2} + D_{12} \cdot Ln(Hct)$$

and

$$A_{14} \cdot Ratio + \frac{B_{14}}{Ratio} + \frac{C_{14}}{Ratio^2} + \frac{D_{14}}{Hct}$$

34. A method of determining oxygen saturation of the blood comprising the following steps:

providing infrared light to the blood;

providing red light to the blood;

measuring the amount of infrared light returned from the blood;

measuring the amount of red light returned from the blood;

utilizing the measurement of infrared light to calculate hematocrit; and

calculating oxygen saturation using the following formula, where E, F, G, H, I, J, and K are constants, R is the ratio of the measurement of infrared to red light returned, and Hct is the percent hematocrit:

$$sO_2 = E \cdot ratio + F/ratio + G/(ratio^2) + H \cdot ratio/Hct + I \cdot Hct + J/Hct + K/(Hct^2)$$

35. A method of determining oxygen saturation to the blood comprising the following steps:

providing infrared light to the blood;

providing red light to the blood;

measuring the amount of infrared light returned from the blood;

measuring the amount of red light returned from the blood;

utilizing the measurement of infrared light to calculate hematocrit; and

calculating oxygen saturation using the following formula, where N, O, P, Q, S, and T are constants, Ratio is the ratio of the measurement of infrared to red light returned, and Hct is the percent hematocrit:

$$sO_2 = N \cdot Ratio + O/Ratio + P/(Ratio^2) + Q \cdot Ratio/Hct + S \cdot Hct + T \cdot Ln(Hct)$$

36. Apparatus for determining oxygen saturation in blood passing through a blood circuit comprising:

means for repeatedly providing light to the blood as it passes through the blood circuit;

means for repeatedly receiving light reflected from the blood at a single distance from the provided light;

means for repeatedly utilizing the received light to approximate the amount of light reflected from the blood at the isobestic wavelength of oxy- and deoxyhemoglobin;

means for repeatedly calculating the hematocrit level of the blood passing through the blood circuit based on the amount of light reflected from the blood at the isobestic wavelength; and

means for repeatedly calculating oxygen saturation in the blood passing through the blood circuit based on the amount of light reflected from the blood and the calculation of hematocrit so that the oxygen saturation determination includes a correction for the hematocrit level of the blood passing through the circuit, calculated according to the amount of light reflected at the isobestic wavelength of oxy- and deoxyhemoglobin.

37. Apparatus according to claim 36 and further comprising:

means for repeatedly providing light at a red wavelength to the blood, wherein said first means for providing light provides light at an infrared wavelength;

means for repeatedly measuring the amount of red light reflected from the blood as the blood passes through the blood circuit; and

means for repeatedly measuring the amount of infrared light reflected from the blood as it passes through the blood circuit

wherein the means for calculating oxygen saturation utilizes the measurements of red and infrared light.

38. Apparatus according to claim 37 and wherein the means for repeatedly providing light are light-emitting diodes, the means for measuring the amount of light is a photodiode and the means for calculating is comprised of software.

39. Apparatus according to claim 38 and wherein the blood is passed through a cuvette, the light-emitting diodes provide light to the blood through fiber-optic cables, and the photodiode receives light through a fiber-optic cable.

40. Apparatus according to claim 38 and further including an LED emitting light at a second infrared wavelength to the blood, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic point.

41. Apparatus according to claim 37 and including software to calculate oxygen saturation level according to the following formula, where E, F, G, H, I, J, and K are constants, Hct is percent hematocrit, and ratio is the ratio of reflected light at the infrared range to that at the red range:

$$sO_2 = E \cdot ratio + F/ratio + G/(ratio^2) + H \cdot ratio/Hct + I \cdot Hct + J/Hct + K/(Hct^2)$$

42. Apparatus according to claim 37 and including software to calculate oxygen saturation level according to the following formula, where N, O, P, Q, S, and T are constants, Hct is percent hematocrit, and Ratio is the ratio of reflected light at the infrared range to that at the red range:

$$sO_2 = N \cdot Ratio + O/Ratio + P/(Ratio^2) + Q \cdot Ratio/Hct + S \cdot Hct + T \cdot Ln(Hct)$$

43. Apparatus according to claim 38 and wherein the software provides more than one formula for the determination of oxygen saturation according to the level of hematocrit.

44. Apparatus according to claim 38 and wherein the software provides more than one formula for the determination of oxygen saturation according to the oxygen saturation level.

45. Apparatus for determining oxygen saturation of blood in a blood circuit comprising:

means for repeatedly measuring light at a wavelength in the red range, of the blood as it passes through the blood circuit;

means for repeatedly measuring reflected light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit;

means for repeatedly calculating hematocrit level in the blood as it passes through the blood circuit based on the measurements of step b); and

means for repeatedly determining oxygen saturation in the blood based on the measurements, and the calculation of hematocrit, and selecting a different formula for the determination according to the level of oxygen saturation.

46. Apparatus according to claim 45 and wherein the means for determining oxygen saturation includes means for selecting a different formula according to the level of hematocrit.

47. A method according to claim 9 wherein the hematocrit level is calculated based on an approximation of the amount of light reflected at the isobestic wavelength on the reflection curve of oxy- and deoxyhemoglobin.

48. Apparatus according to claim 46 and wherein the means for calculating hematocrit includes means for calculating using an approximation of the amount of light reflected at the isobestic wavelength of oxy- and deoxyhemoglobin.

49. Apparatus according to claim 48 and wherein the wavelength in the infrared range is at the isobestic wavelength.

50. Apparatus according to claim 46 and wherein the means for calculating oxygen saturation includes means for calculating the ratio of the measurement of infrared light to the measurement of red light.

51. Apparatus according to claim 48 and wherein the means for repeatedly providing light are light-emitting diodes, the means for measuring the amount of light is a photodiode, and the means for calculating is comprised of software.

52. Apparatus according to claim 51 and wherein the blood is passed through a cuvette, the light-emitting diodes provide

light to the blood through fiber-optic cables, and the photodiode receives light through a fiber-optic cable.

53. Apparatus according to claim 51 and further including an LED emitting light at a second infrared wavelength to the blood, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic wavelength.

54. Apparatus for determining oxygen saturation in blood in a blood circuit comprising:

means for repeatedly measuring light at a wavelength in the red range reflected from the blood as it passes through the blood circuit;

means for repeatedly measuring light at a wavelength in the infrared range reflected from the blood as it passes through the blood circuit; and

means for repeatedly calculating oxygen saturation in the blood based on the measurements, using a different formula for the determination of oxygen saturation according to the level of hematocrit in the blood.

55. Apparatus according to claim 54 and further comprising means for repeatedly calculating hematocrit level of the blood as it passes through the blood circuit and wherein the means for calculating oxygen saturation includes means for correcting the oxygen saturation calculation for the hematocrit level.

56. Apparatus according to claim 55 further comprising means for providing red light to the blood and means for providing infrared light to the blood, and wherein the means for calculating hematocrit includes a means for approximating the amount of reflected light at the isobestic wavelength on the reflection curves of deoxy- and oxyhemoglobin.

57. Apparatus according to claim 55 and wherein the means for repeatedly providing light are light-emitting diodes, the means for measuring the amount of light is a photodiode, and the means for calculating is comprised of software.

58. Apparatus according to claim 55 and wherein the blood is passed through a cuvette, the light-emitting diodes provide light to the blood through fiber-optic cables, and the photodiode receives light through a fiber-optic cable.

59. Apparatus according to claim 58 and further comprising a light-emitting diode for providing light at a second infrared wavelength to the blood and means for repeatedly measuring the amount of the second infrared wavelength reflected from the blood, where the two infrared wavelengths are symmetrically disposed on different sides of the isobestic point.

60. Apparatus according to claim 38, 51 or 58 and wherein the light-emitting diodes emit light sequentially, and a central processing unit controls the apparatus.

61. Apparatus according to claim 38, 51 or 58 and wherein the red light is at about 660 nm and the infrared light is at about 830 nm, and a separate light-emitting diode provides light to the blood at about 810 nm.

62. Apparatus according to claim 39, 52 or 58 and wherein the red light is at about 660 nm and the infrared light is at about the isobestic point on the reflection curve of oxy- and deoxyhemoglobin.

63. Apparatus according to claim 39, 52 or 58 and wherein the providing fiber-optic cables are all equidistant from the receiving fiber-optic cable.

64. Apparatus according to claim 48, 51 or 59 and wherein the software provides an approximation of the amount of light reflected at the isobestic point according to the following formula, where R equals the amount of reflected light:

$$R_{ISOBESTIC} = \frac{R_{FIRST\ INFRARED} + R_{SECOND\ INFRARED}}{2}$$

65. A method according to claim 48, 51 or 59 and wherein software provides an approximation of the amount of light reflected at the isobestic point according to the following formula, where R equals the amount of reflected light:

$$R_{ISOBESTIC} = R_{FIRST\ INFRARED} \times R_{SECOND\ INFRARED}$$

66. Apparatus according to claim 38, 51 or 58 and wherein the software provides a calculation of hematocrit according to the following formula:

$$Hct = A \cdot R_{ISOBESTIC} + B \cdot R_{ISOBESTIC}^2 + \frac{C}{R_{ISOBESTIC}} + \frac{D}{R_{ISOBESTIC}^2}$$

67. Apparatus according to claim 38, 51 or 58 and wherein the software provides a calculation of hematocrit according to the following formula where L and M are constants and $R_{ISOBESTIC}$ approximates the amount of light reflected from the blood at the isobestic wavelength:

$$Hct = Exp\ (L \cdot R_{ISOBESTIC} + M/Ln(R_{ISOBESTIC}^2))$$

68. Apparatus according to claim 39, 52 or 58 and wherein the providing fiber-optic cables are equidistant from the receiving fiber-optic cable.

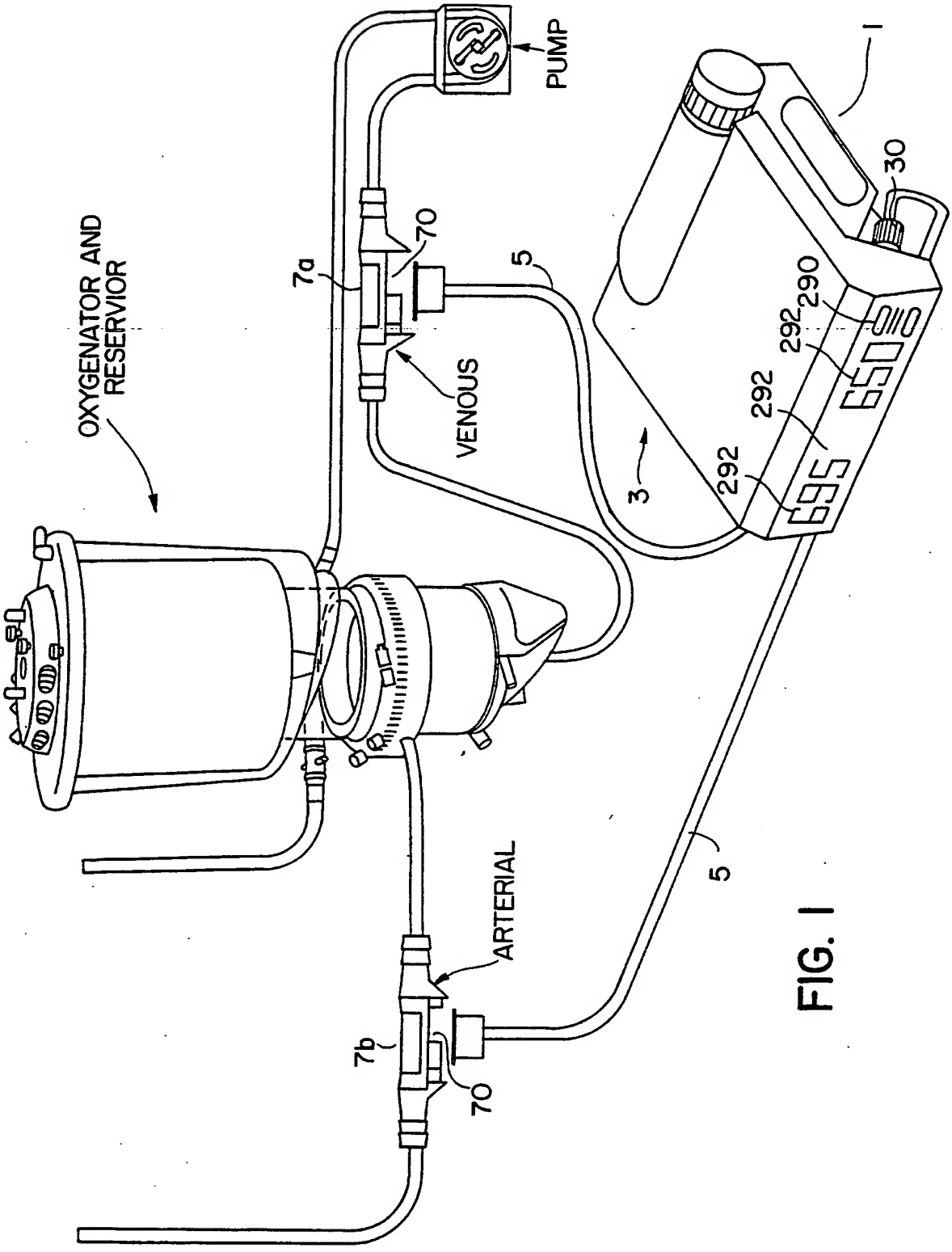

PUMP
1
30
OXYGENATOR AND RESERVIOR
70
7a
5
VENOUS
290
292
292
292
3
ARTERIAL
5
7b
70

FIG. 1

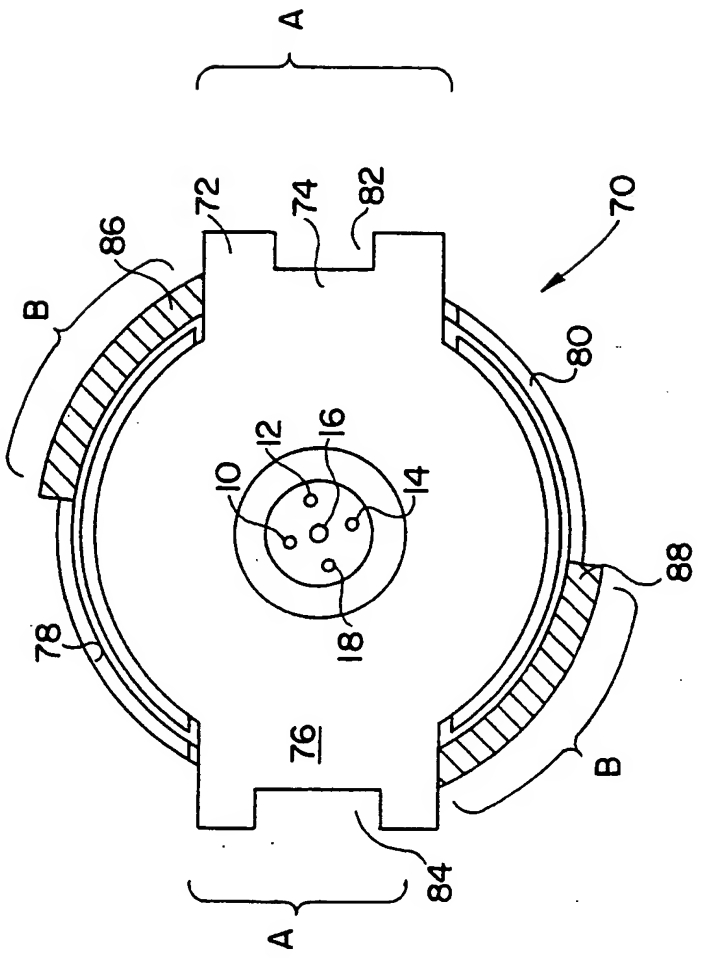


FIG. 2A

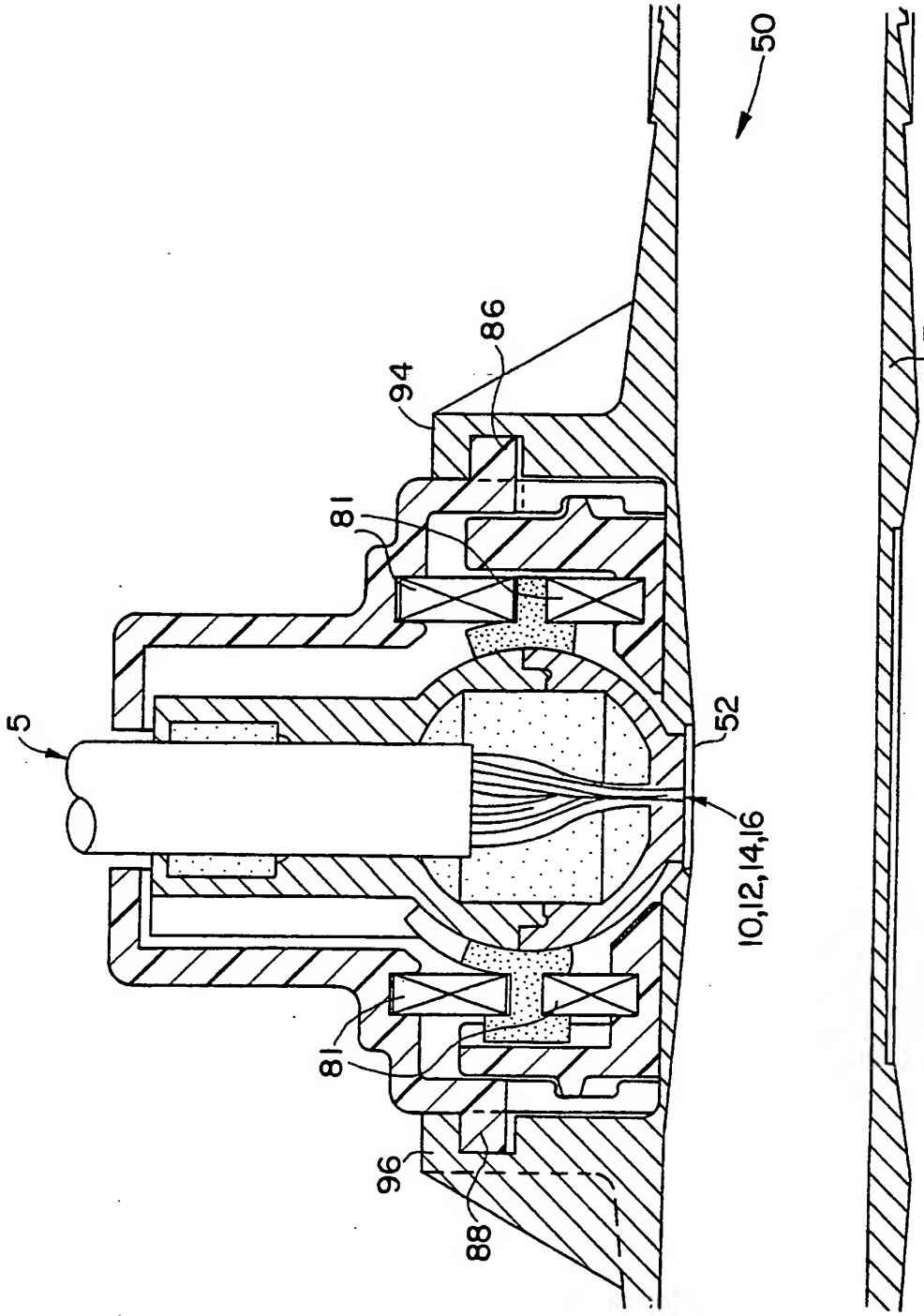


FIG. 2B

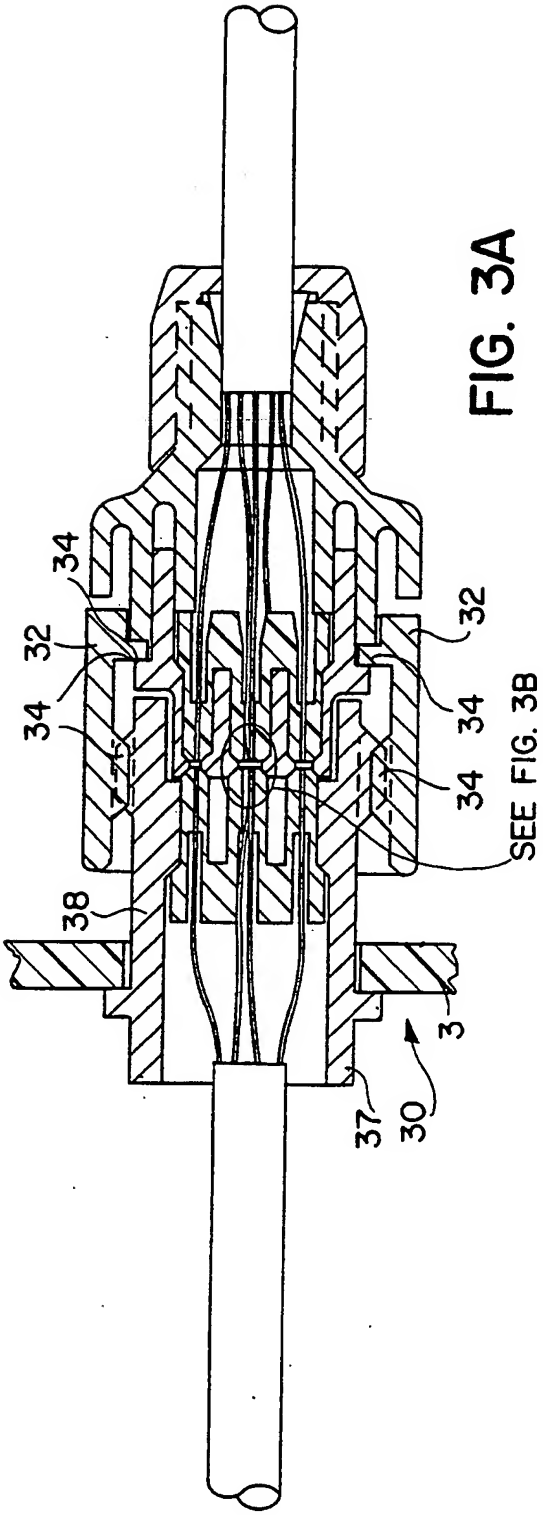


FIG. 3A

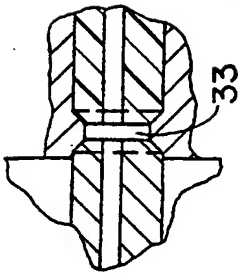


FIG. 3B

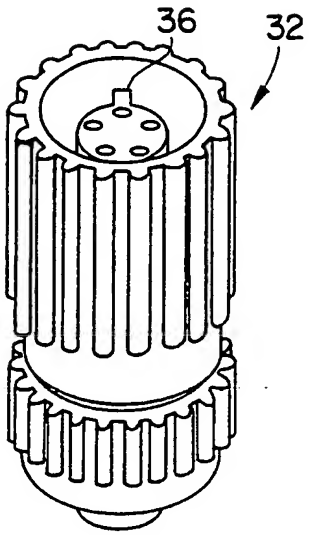


FIG. 3C

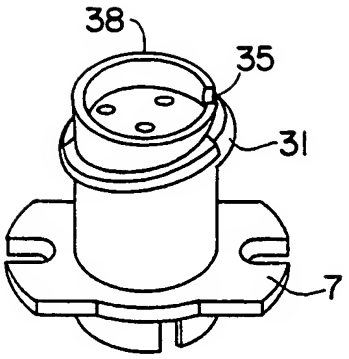
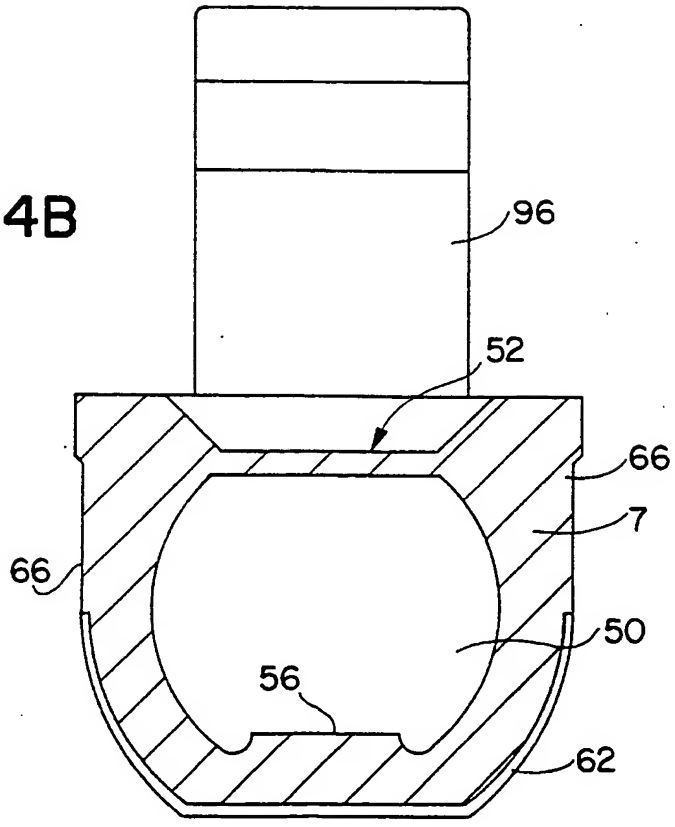


FIG. 3D

FIG. 4B



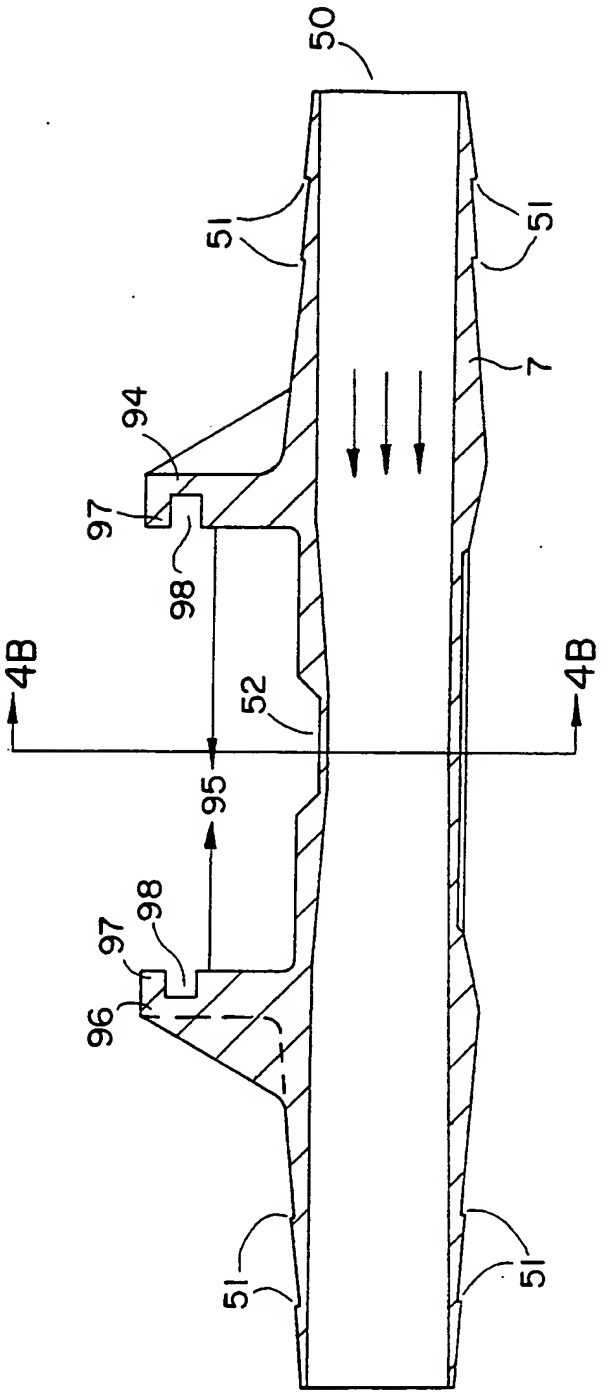


FIG. 4A

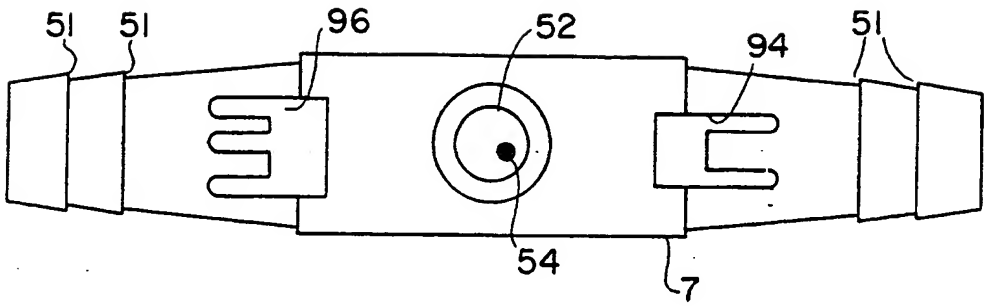


FIG. 4C

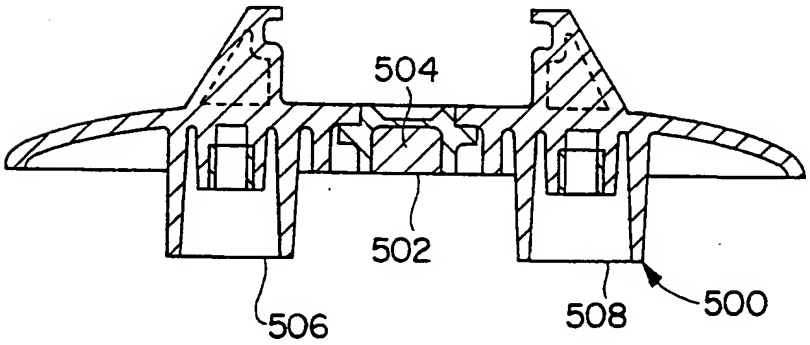


FIG. 4D

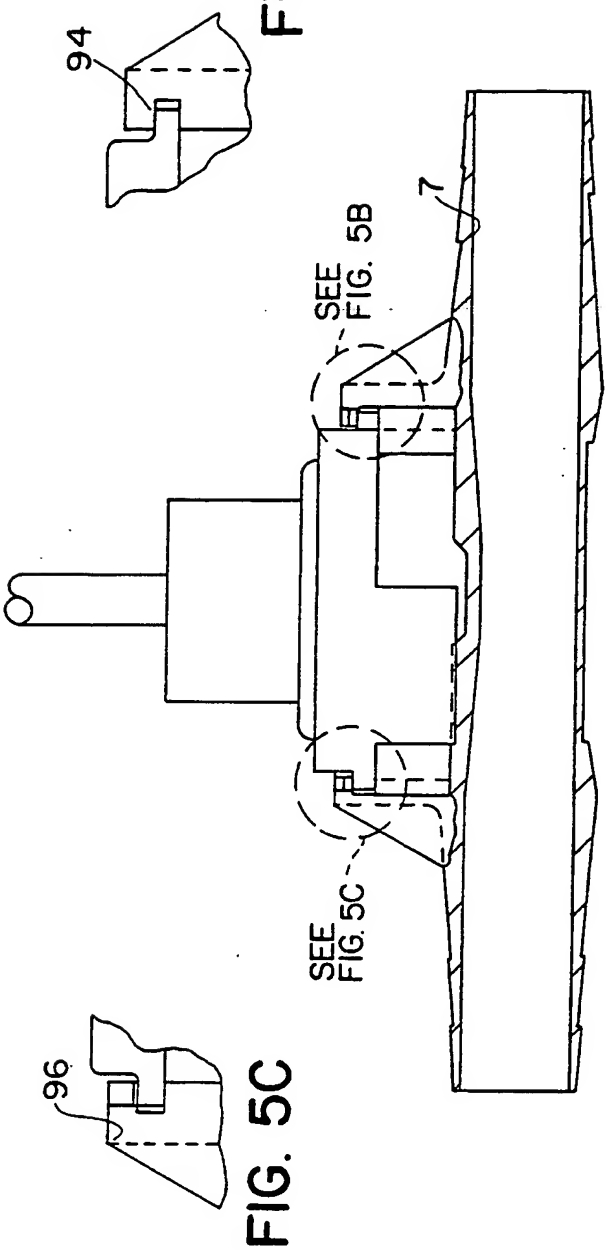


FIG. 5B

FIG. 5A

FIG. 5C

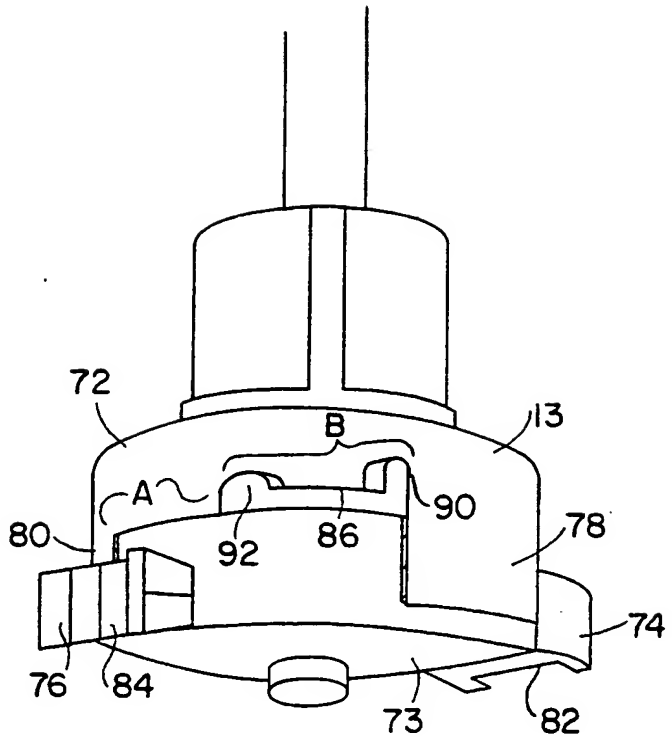


FIG. 5D

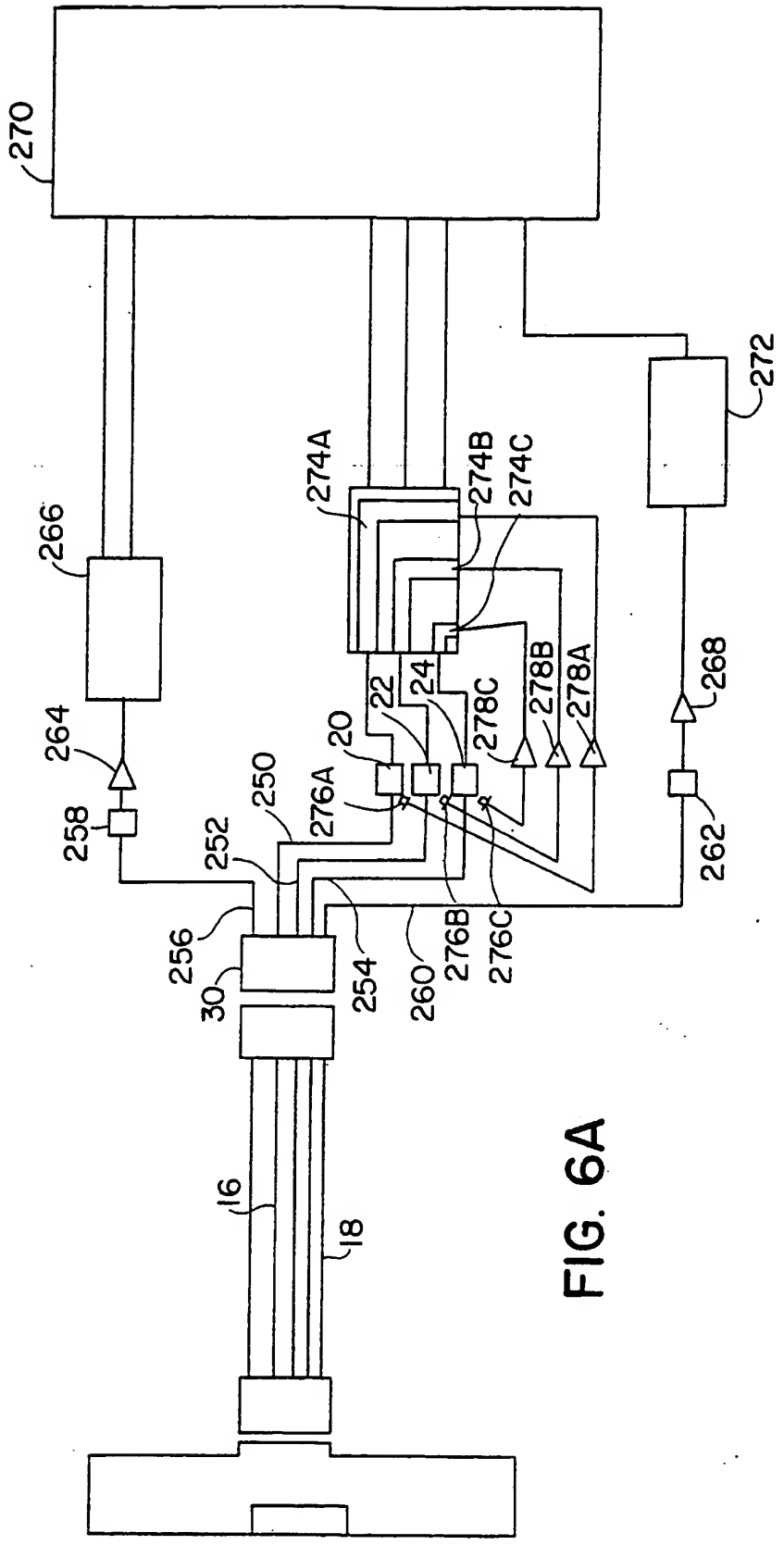

270
272
274A
274B
274C
266
268
264
22
24
278C
278B
278A
20
250
276A
258
252
262
256
254
260
276B
276C
30
16
18

FIG. 6A

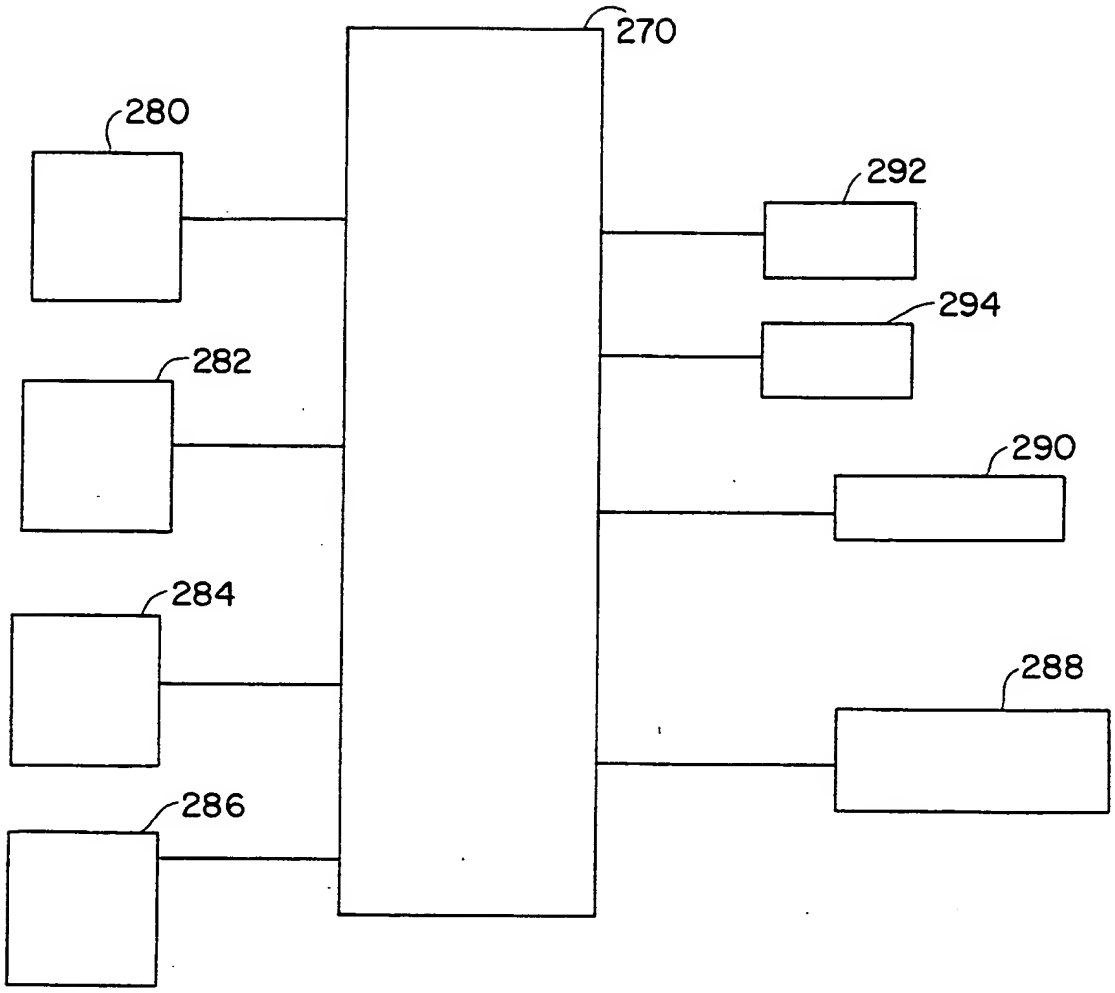


FIG. 6B

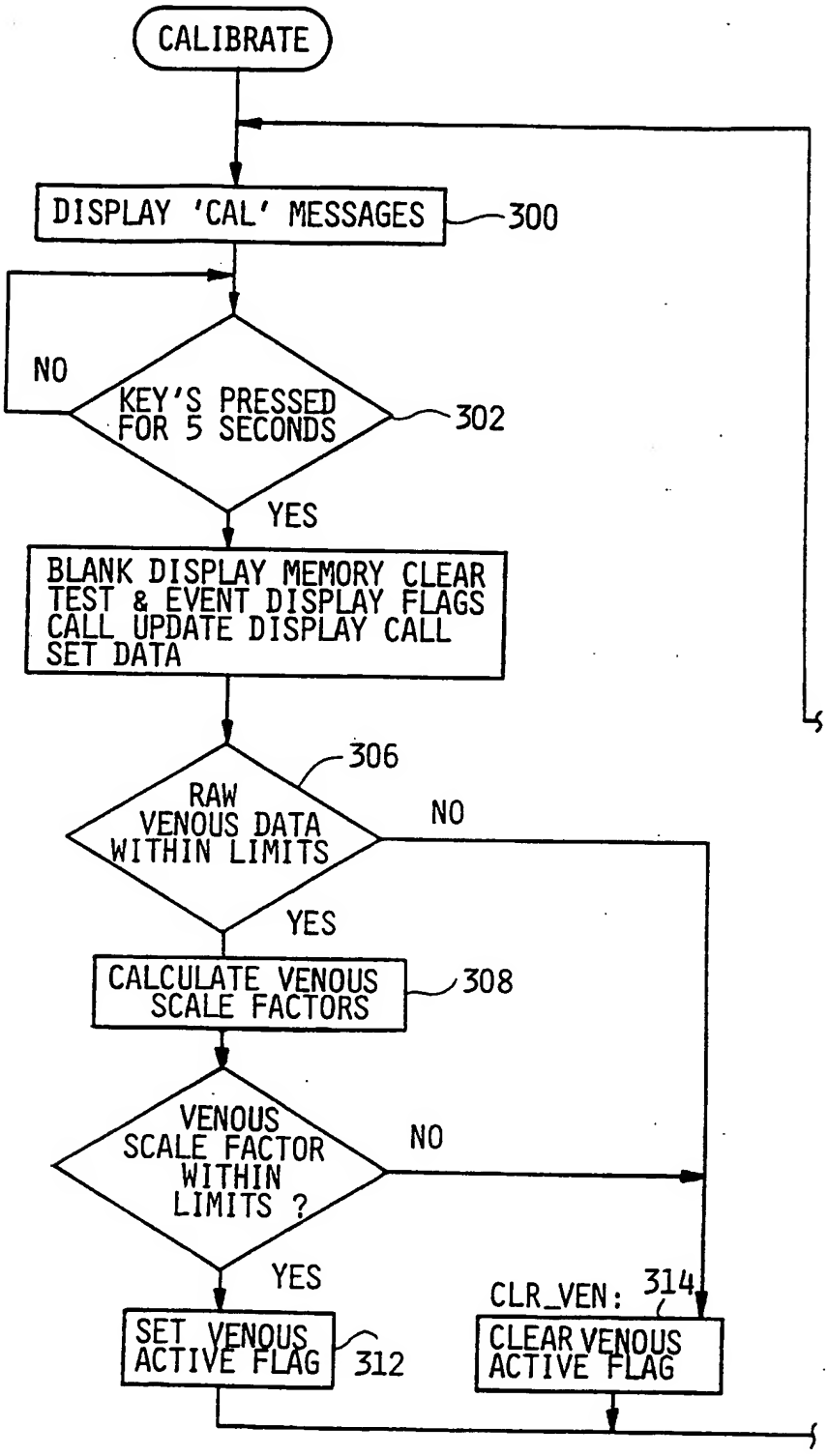

CALIBRATE
DISPLAY 'CAL' MESSAGES
300
NO
KEY'S PRESSED FOR 5 SECONDS
302
YES
BLANK DISPLAY MEMORY CLEAR TEST & EVENT DISPLAY FLAGS CALL UPDATE DISPLAY CALL SET DATA
306
RAW VENOUS DATA WITHIN LIMITS
NO
YES
CALCULATE VENOUS SCALE FACTORS
308
VENOUS SCALE FACTOR WITHIN LIMITS ?
NO
YES
SET VENOUS ACTIVE FLAG
312
CLR_VEN:
314
CLEAR VENOUS ACTIVE FLAG

FIG. 7A-1

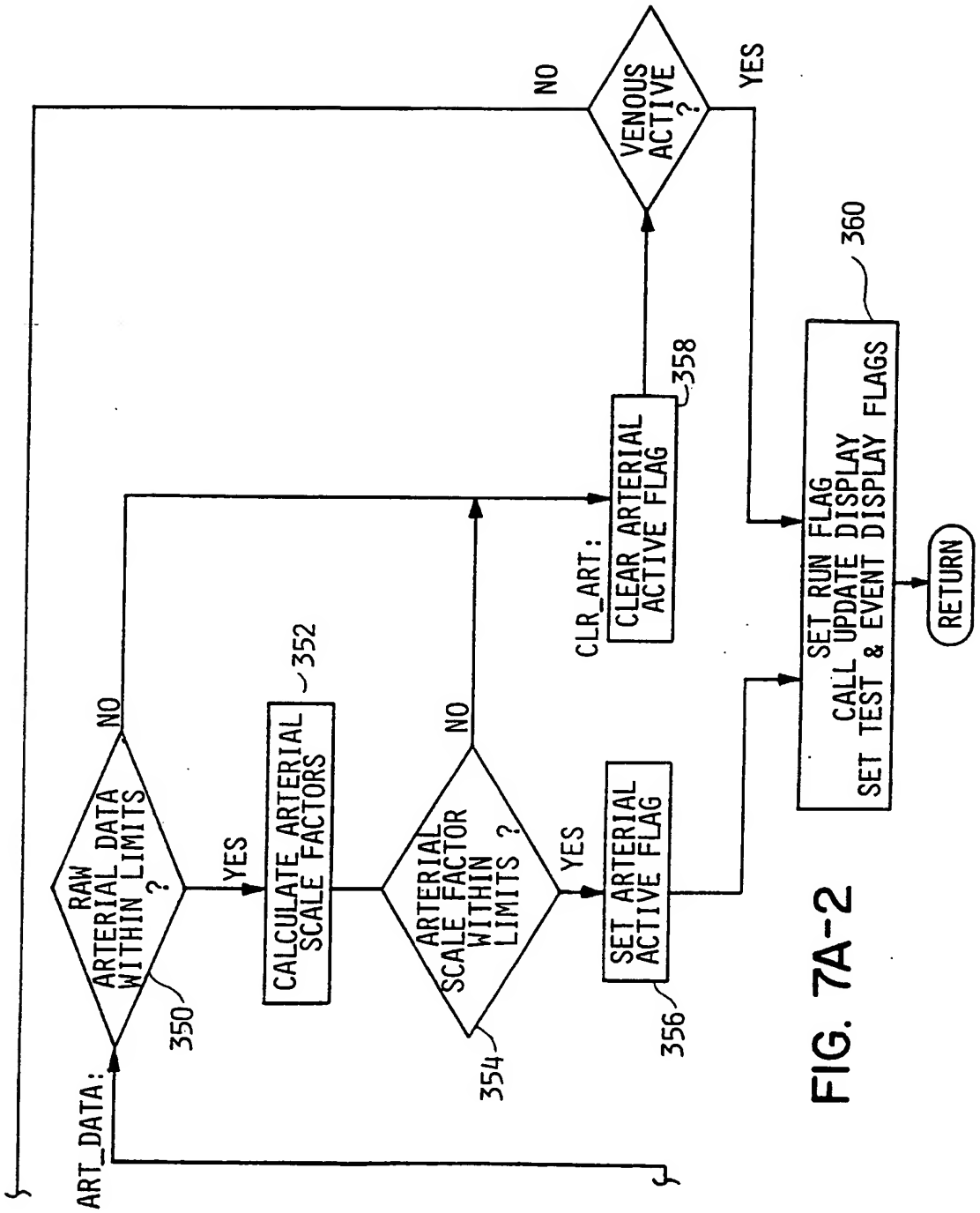

ART_DATA:
RAW ARTERIAL DATA WITHIN LIMITS ?
350
NO
YES
CALCULATE ARTERIAL SCALE FACTORS
352
ARTERIAL SCALE FACTOR WITHIN LIMITS ?
354
NO
YES
SET ARTERIAL ACTIVE FLAG
356
CLR_ART:
CLEAR ARTERIAL ACTIVE FLAG
358
VENOUS ACTIVE ?
NO
YES
SET RUN FLAG
CALL UPDATE DISPLAY
SET TEST & EVENT DISPLAY FLAGS
360
RETURN

FIG. 7A-2

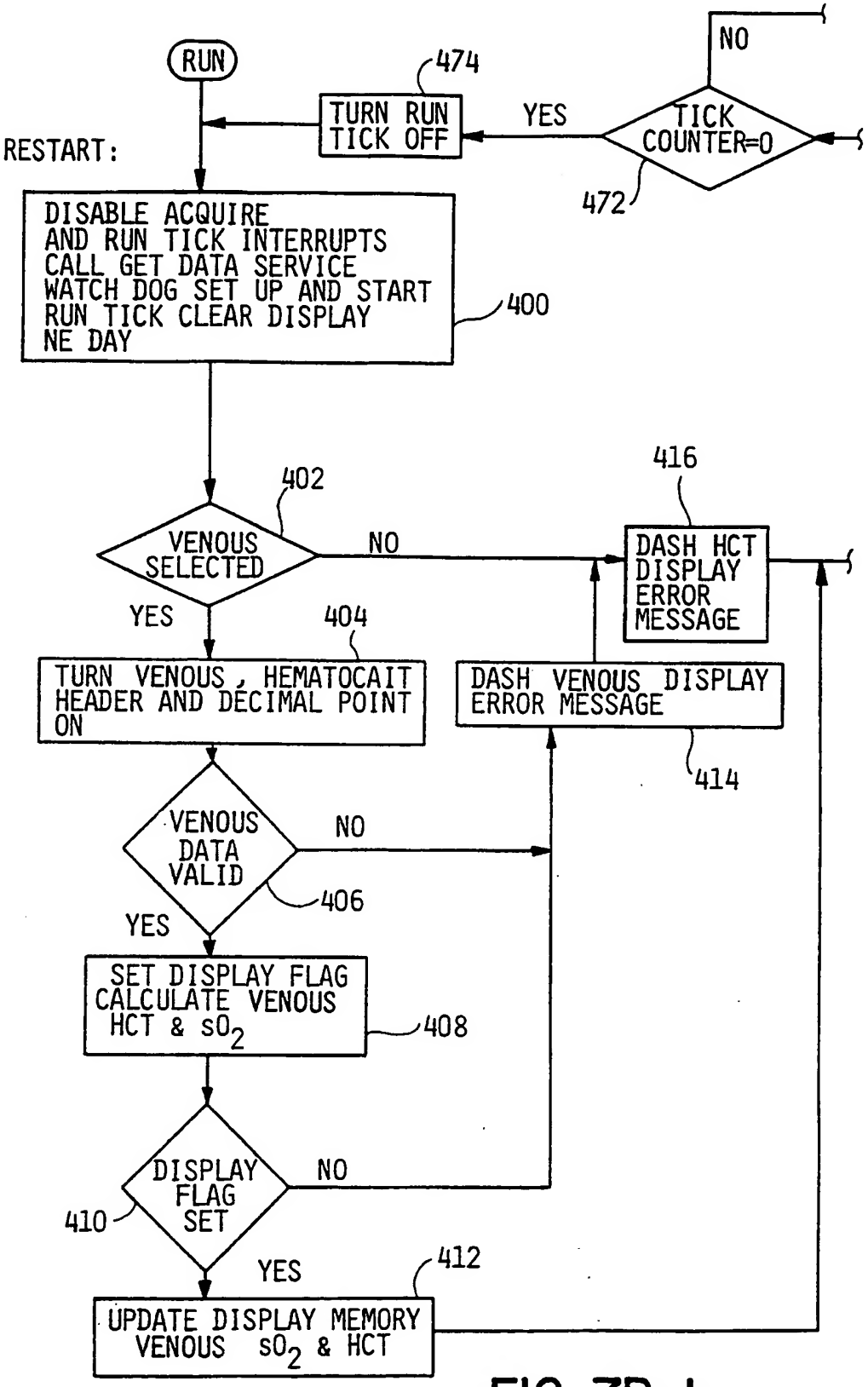

RUN
RESTART:
474
TURN RUN TICK OFF
YES
TICK COUNTER=0
NO
472
DISABLE ACQUIRE AND RUN TICK INTERRUPTS CALL GET DATA SERVICE WATCH DOG SET UP AND START RUN TICK CLEAR DISPLAY NE DAY
400
402
VENOUS SELECTED
NO
416
DASH HCT DISPLAY ERROR MESSAGE
YES
404
TURN VENOUS , HEMATOCAIT HEADER AND DECIMAL POINT ON
DASH VENOUS DISPLAY ERROR MESSAGE
414
VENOUS DATA VALID
NO
406
YES
SET DISPLAY FLAG CALCULATE VENOUS HCT & sO_2
408
DISPLAY FLAG SET
NO
410
YES
412
UPDATE DISPLAY MEMORY VENOUS sO_2 & HCT

FIG. 7B-1

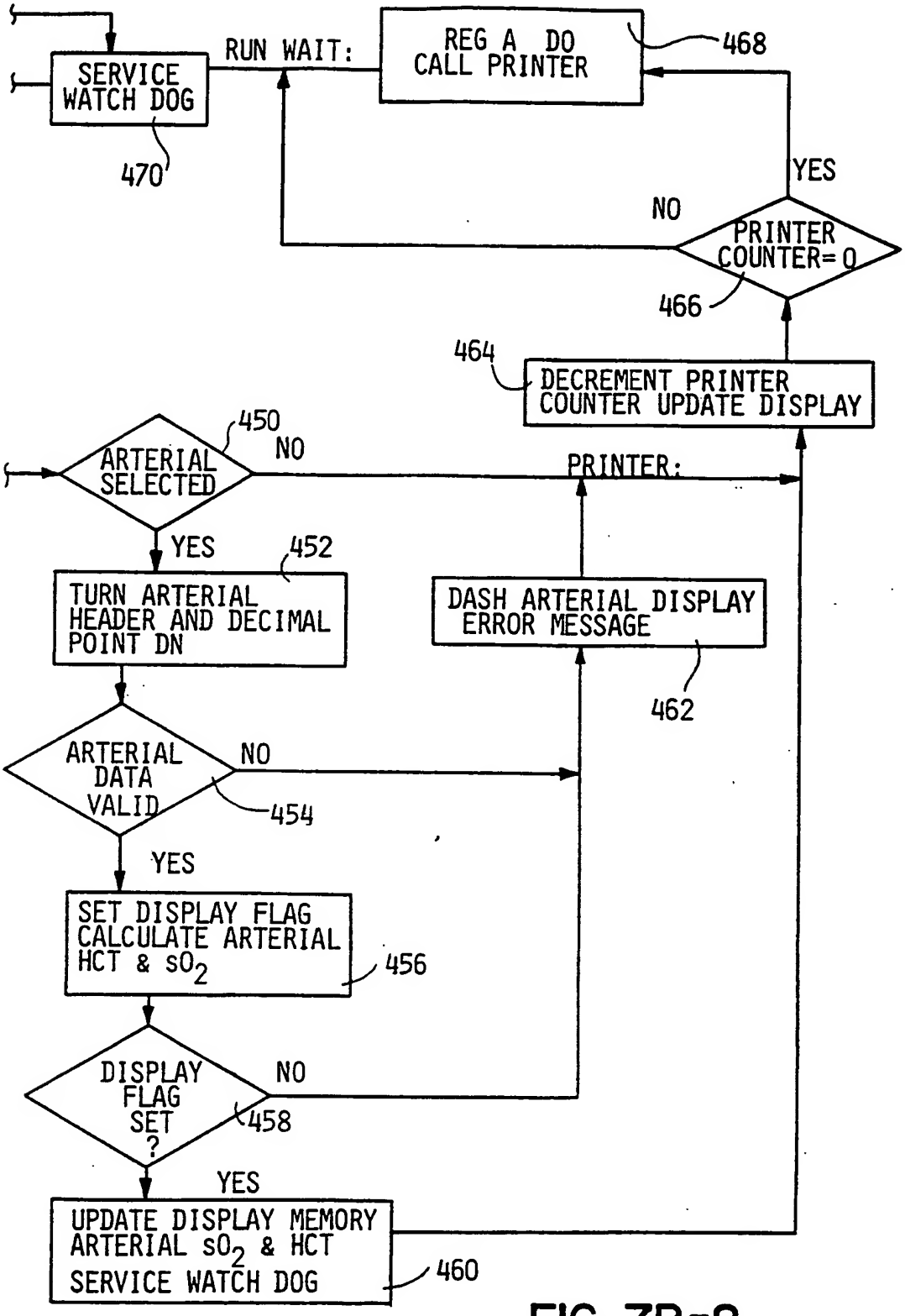

SERVICE WATCH DOG
470
RUN WAIT:
REG A DO CALL PRINTER
468
YES
NO
PRINTER COUNTER=0
466
464
DECREMENT PRINTER COUNTER UPDATE DISPLAY
450
ARTERIAL SELECTED
NO
PRINTER:
YES
452
TURN ARTERIAL HEADER AND DECIMAL POINT DN
DASH ARTERIAL DISPLAY ERROR MESSAGE
462
ARTERIAL DATA VALID
NO
454
YES
SET DISPLAY FLAG CALCULATE ARTERIAL HCT & sO_2
456
DISPLAY FLAG SET ?
NO
458
YES
UPDATE DISPLAY MEMORY ARTERIAL sO_2 & HCT
SERVICE WATCH DOG
460

FIG. 7B-2

sO_2 EQUATIONS PARTITIONING B[illegible]ct & RATIO

DECISION POINT		EQN #	sO_2 EQUATION
Hct RANGE	RATIO		
LEVEL 1	$Rat \geq R_1$	1	$A_1 \cdot Rat + \frac{B_1}{Rat} + C_1 \cdot (Rat^2) + D_1 \cdot Ln(Hct)$
	$Rat \geq R_2$	2	$\frac{A_2}{Rat} + \frac{B_2}{(Rat^2)} + C_2 \cdot Ln(Hct)$
	$Rat \geq R_3$	3	$A_3 \cdot Rat + \frac{B_3}{Rat} + \frac{C_3}{(Rat^2)} + D_3 \cdot Ln(Hct)$
	$Rat < R_3$	4	$A_4 \cdot Rat + \frac{B_4}{Rat} + \frac{C_4}{(Rat^2)} + D_4 \cdot Ln(Hct)$
LEVEL 2	$Rat \geq R_4$	5	$A_5 \cdot Rat + \frac{B_5}{Rat} + \frac{C_5}{(Rat^2)} + D_5 \cdot Ln(Hct)$
	$Rat \geq R_5$	6	$A_6 \cdot Rat + \frac{B_6}{Rat} + \frac{C_6}{(Rat^2)} + \frac{D_6}{Hct}$
	$Rat \geq R_6$	7	$A_7 \cdot Rat + \frac{B_7}{Rat} + C_7 \cdot Ln(Hct) + D_7 \cdot \frac{Hct}{Rat}$
	$Rat < R_6$	8	$A_8 \cdot Rat + \frac{B_8}{Rat} + \frac{C_8}{(Rat^2)} + D_8 \cdot Ln(Hct)$
LEVEL 3	$Rat \geq R_7$	9	$A_9 \cdot Rat + \frac{B_9}{Rat} + \frac{C_9}{(Rat^2)} + D_9 \cdot \frac{Rat}{Hct}$
	$Rat \geq R_8$	10	$A_{10} \cdot Rat + \frac{B_{10}}{Rat} + \frac{C_{10}}{(Rat^2)} + D_{10} \cdot Ln(Hct) + E_{10} \cdot \frac{Hct}{Rat}$
	$Rat \geq R_9$	11	$A_{11} \cdot Rat + \frac{B_{11}}{Rat} + C_{11} \cdot Ln(Hct) + D_{11} \cdot \frac{Hct}{Rat}$
	$Rat < R_9$	12	$A_{12} \cdot Rat + \frac{B_{12}}{Rat} + \frac{C_{12}}{(Rat^2)} + D_{12} \cdot Ln(Hct)$
LEVEL 4	$Rat \geq R_{10}$	13	$A_{13} \cdot Rat + \frac{B_{13}}{Rat} + \frac{C_{13}}{(Rat^2)} + D_{13} \cdot \frac{Rat}{Hct}$
	$Rat \geq R_{11}$	14	$A_{14} \cdot Rat + \frac{B_{14}}{Rat} + \frac{C_{14}}{(Rat^2)} + \frac{D_{14}}{Hct}$
	$Rat \geq R_{12}$	15	$A_{15} \cdot Rat + \frac{B_{15}}{Rat} + C_{15} \cdot Ln(Hct) + D_{15} \cdot \frac{Hct}{Rat}$
	$Rat < R_{12}$	16	$\frac{A_{16}}{Rat} + \frac{B_{16}}{(Rat^2)} + C16 \cdot Ln(Hct)$

WHERE:
Rat=RATIO IR/RED
A_i-E_i=COEFFICIENTS
Hct=CALCULATED HEMATOCRIT
Hct LEVELS: 1=HIGHEST TO 4=LOWEST RANGE

FIG. 8A

sO_2 EQUATIONS PARTITIONING BY Hct

DECISION POINT	EQN #	sO_2 EQUATION
Hct ≥ LEVEL 1	1	$A_1 \cdot Rat + \frac{B_1}{Rat} + \frac{C_1}{(Rat^2)} + D_1 \cdot \frac{Rat}{Hct} + \frac{E_1}{Hct} + \frac{F_1}{Hct^2}$
Hct ≥ LEVEL 2	2	$A_2 \cdot Rat + \frac{B_2}{Rat} + \frac{C_2}{(Rat^2)} + D_2 \cdot \frac{Rat}{Hct} + \frac{E_2}{Hct} + \frac{F_2}{Hct^2}$
Hct ≥ LEVEL 3	3	$A_3 \cdot Rat + \frac{B_3}{Rat} + \frac{C_3}{(Rat^2)} + D_3 \cdot \frac{Rat}{Hct} + \frac{E_3}{Hct} + \frac{F_3}{Hct^2} + G_3 \cdot Hct$
Hct < LEVEL 3	4	$A_4 \cdot Rat + \frac{B_4}{Rat} + \frac{C_4}{(Rat^2)} + D_4 \cdot \frac{Rat}{Hct} + \frac{E_4}{Hct} + \frac{F_4}{Hct^2} + G_4 \cdot Hct$

WHERE:

Rat=RATIO IR/RED

A_1-G_1=COEFFICIENTS

Hct=CALCULATED HEMATOCRIT

Hct LEVELS: 1=HIGHEST TO 4=LOWEST RANGE

FIG. 8B

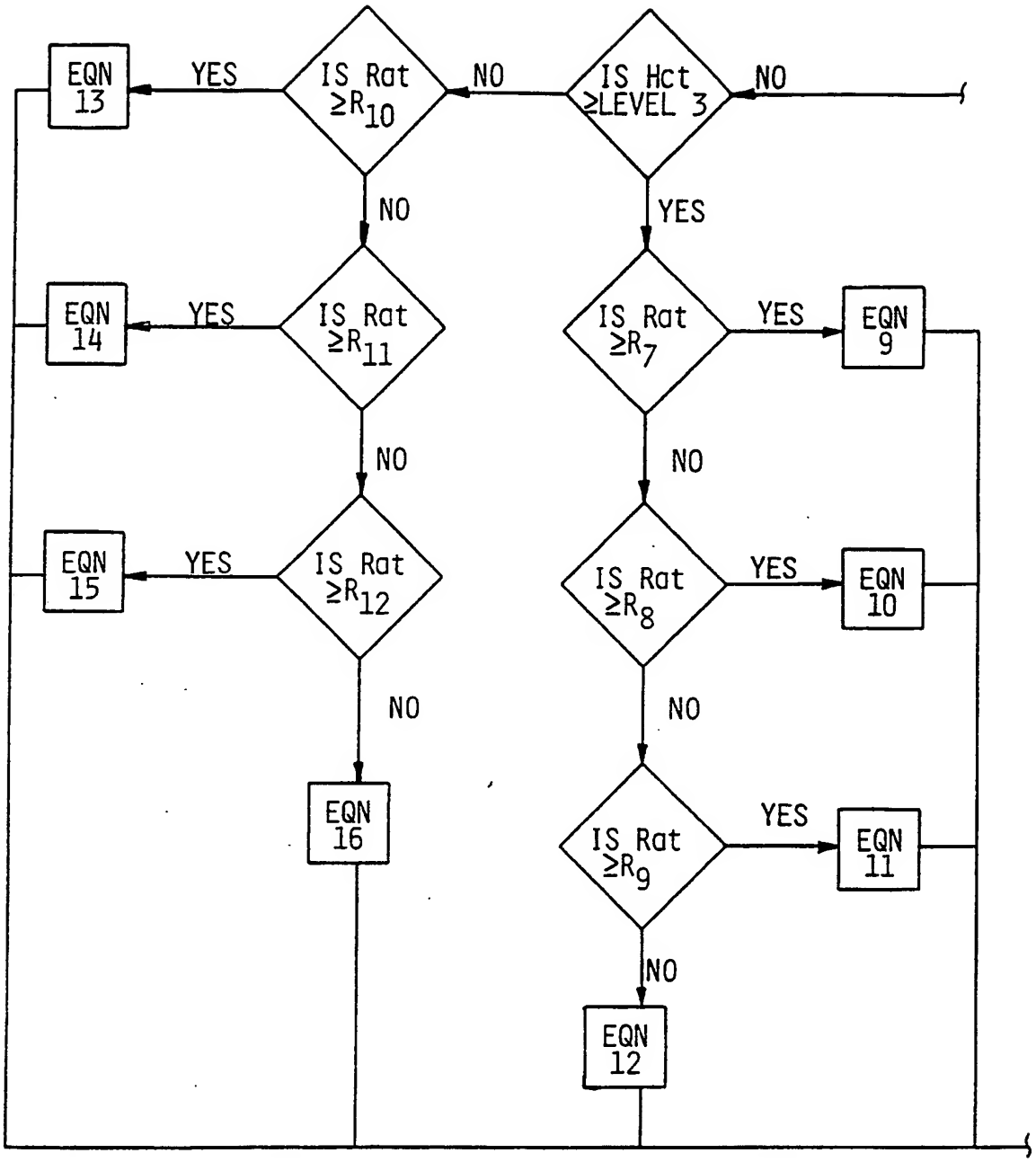

IS Hct ≥LEVEL 3
NO
YES
IS Rat ≥R_{10}
NO
YES
EQN 13
IS Rat ≥R_{11}
NO
YES
EQN 14
IS Rat ≥R_7
YES
EQN 9
IS Rat ≥R_{12}
NO
YES
EQN 15
IS Rat ≥R_8
YES
EQN 10
EQN 16
IS Rat ≥R_9
NO
YES
EQN 11
EQN 12

FIG. 8C-1

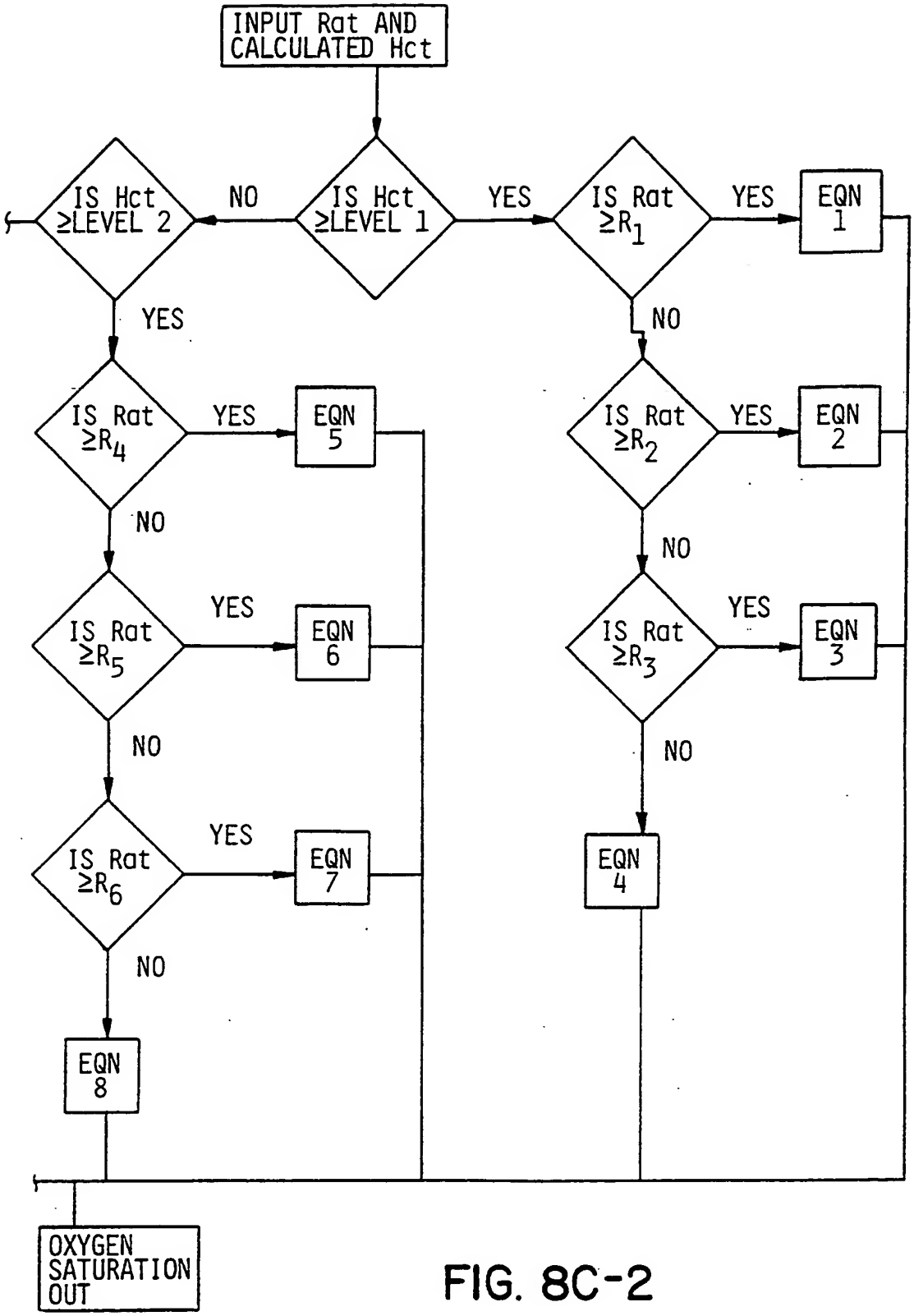

INPUT Rat AND CALCULATED Hct
IS Hct ≥LEVEL 1
IS Hct ≥LEVEL 2
NO
YES
IS Rat ≥R_1
YES
EQN 1
NO
IS Rat ≥R_2
YES
EQN 2
NO
IS Rat ≥R_3
YES
EQN 3
NO
EQN 4
YES
IS Rat ≥R_4
YES
EQN 5
NO
IS Rat ≥R_5
YES
EQN 6
NO
IS Rat ≥R_6
YES
EQN 7
NO
EQN 8
OXYGEN SATURATION OUT

FIG. 8C-2

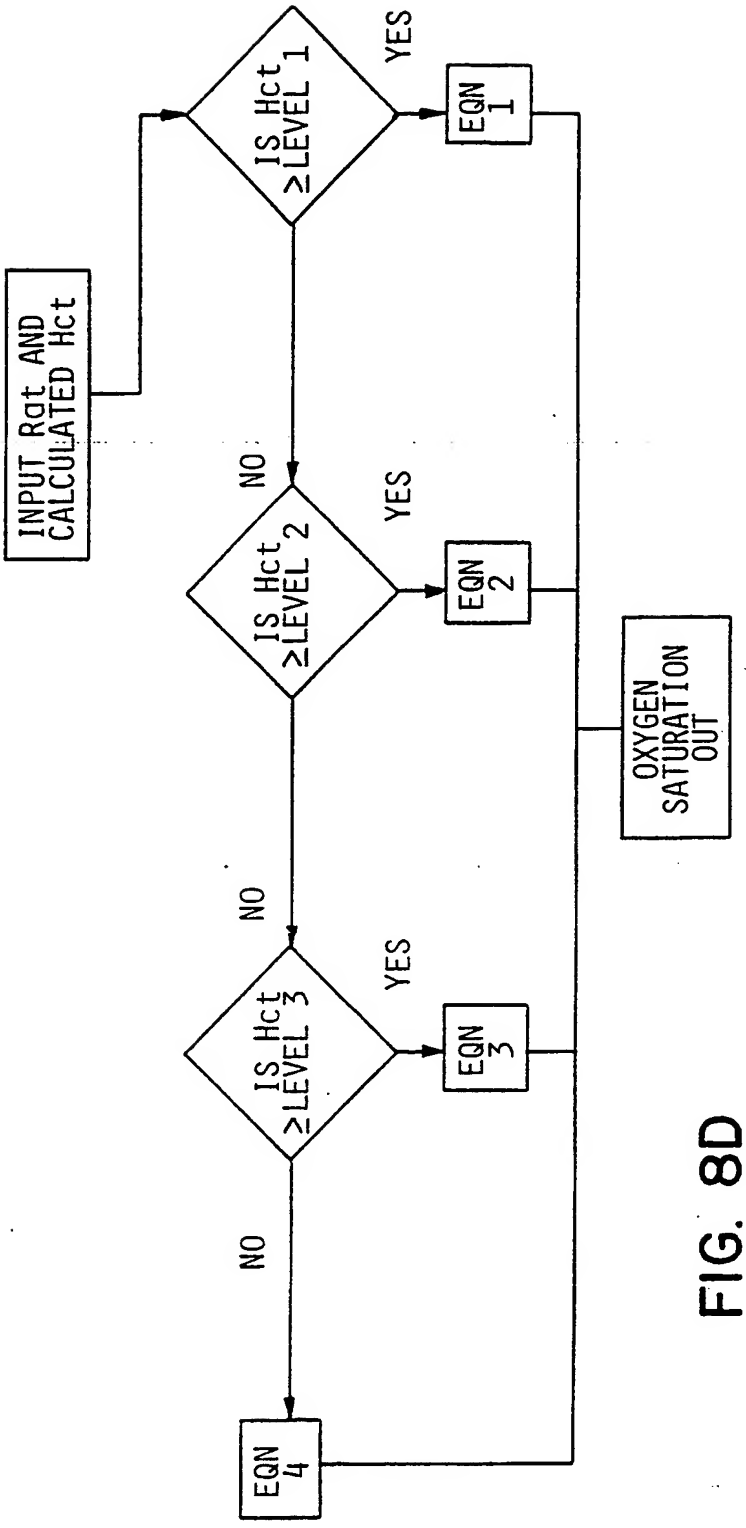

INPUT Rat AND CALCULATED Hct
IS Hct ≥LEVEL 1
YES
EQN 1
NO
IS Hct ≥LEVEL 2
YES
EQN 2
NO
IS Hct ≥LEVEL 3
YES
EQN 3
NO
EQN 4
OXYGEN SATURATION OUT

FIG. 8D

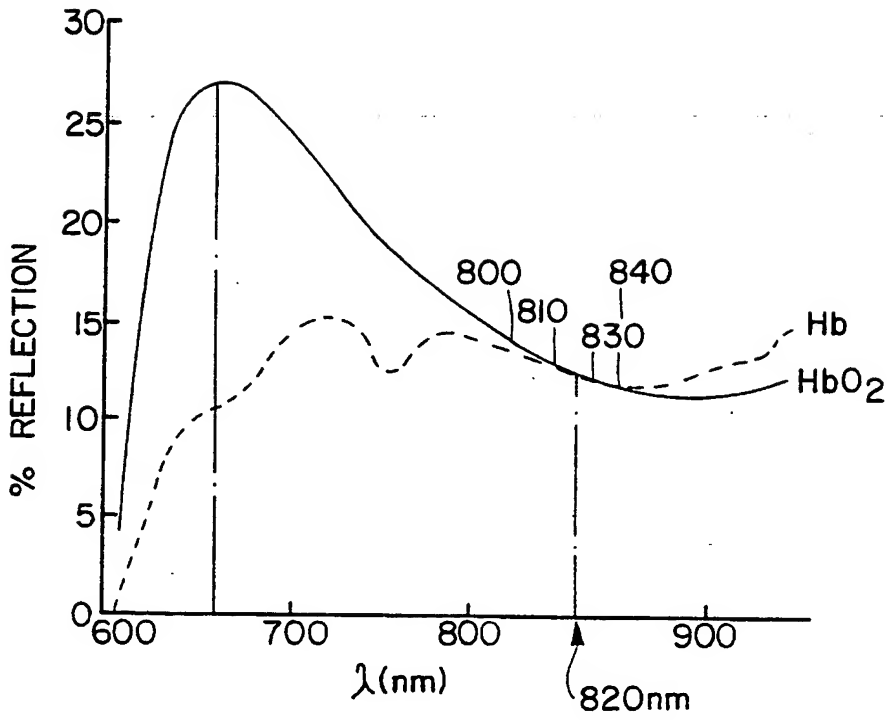

30
25
20
15
10
5
0
% REFLECTION
600
700
800
900
λ(nm)
820nm
800
810
830
840
Hb
HbO2

FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 92/08396

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/00; G01N21/31

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; G01N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	US,A,4 776 340 (B. L. MORAN ET AL.) 11 October 1988 cited in the application	1-3, 13-16, 22,24, 34-38,60
Y	see column 7, line 59 - line 66	6,8-10, 12,25, 43,45, 46,50, 54,55
A	see column 8, line 27 - line 40	5,20,21, 23,41, 42, 47-49, 51,56, 57,61, 62,66
	see column 17, line 3 - column 18, line 26; claims	

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° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
19 JANUARY 1993	02. 02. 93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	FONTENAY P.H.

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	US,A,4 651 741 (PASSAFARO) 24 March 1987 cited in the application	6,8-10, 12,25, 43,45, 46,50, 54,55
A	see the whole document	5,13,14, 22-24, 34-38, 41,42, 51,57, 61,62

Y	US,A,5 048 524 (W. H. BAILEY) 17 September 1991	1-3, 34-38, 41,42
A	see abstract	8,10, 13-16, 22,23, 39,45, 51,52, 54,55, 57,58
A	see column 2, line 52 - column 3, line 30 see column 8, line 13 - line 33 see column 9, line 4 - line 66; figures 1-5	60-62

Y	EP,A,0 380 664 (TERUMO K. K.) 8 August 1990	1-3, 34-38, 41,42
A	see page 2, line 23 - page 5, line 3	10,13, 14,22, 23,45, 51,54, 57,60-62
	see page 27, line 4 - line 16 see page 32, line 10 - page 35, line 23	

A	WO,A,9 007 905 (FUTREX INC.) 26 July 1990 see page 14, line 26 - page 15, line 18; figure 6	4,11,17, 40,52,59

A	US,A,4 745 279 (M. N. KARKAR ET AL.) 17 May 1988 cited in the application	1,8,14, 15, 34-39, 45, 47-49, 51,52, 55,57,62
	see abstract; claims	

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 15, no. 140 (P-1188)9 April 1991 & JP,A,30 18 742 (TERUMO CORP) see abstract	
P,X	US,A,5 066 859 (M. N. KARKAR ET AL.) 19 November 1991	1-3, 34-39, 60,62, 63,68
P,A	see abstract	8,10,13, 14,22, 23,41, 45,51, 52,54, 55,57
P,A	see column 2, line 34 - column 3, line 28 see column 6, line 47 - column 7, line 5 see column 13, line 42 - line 55; claim 25; figures	58,61

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9208396
SA 65968

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 19/01/93
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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US-A-5066859	19-11-91	None	

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